Comparative Effectiveness Review
Number 165

Treatments for Fecal Incontinence

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Number 165

Treatments for Fecal Incontinence

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Prepared by:
Minnesota Evidence-based Practice Center
Minneapolis, MN

Investigators:
Mary L. Forte, Ph.D., D.C.
Katherine E. Andrade, M.P.H.
Mary Butler, Ph.D., M.B.A.
Ann C. Lowry, M.D.
Donna Z. Bliss, Ph.D., R.N.
Joanne L. Slavin, Ph.D., R.D.
Robert L. Kane, M.D.

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

Richard G. Kronick, Ph.D.
Director
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director
Evidence-based Practice Center Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Arlene Bierman, M.D., M.S.
Director
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Karen C. Lee, M.D., M.P.H.
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of Key Informants who provided input to this report follows:

Adil E. Bharucha, M.B.B.S., M.D.
Gastroenterology
Mayo Clinic
Rochester, MN

Cheryle B. Gartley
Consumer Representative/Advocate
President, The Simon Foundation for Continence
Chicago, IL

Debra Hagerty, D.N.P., R.N., NHA, FACDONA
National Association Directors of Nursing Administration in Long Term Care
Armstrong Atlantic State University
Savannah, GA

Tracy L. Hull, M.D.
Colorectal Surgery
Cleveland Clinic Foundation
Cleveland, OH

Anders Mellgren, M.D., Ph.D., FACS, FASCRS
American Society of Colon and Rectal Surgeons
University of Illinois
Chicago, IL

Susan M. Miller, M.D.
Centers for Medicare & Medicaid Services
Baltimore, MD

Christine Norton, Ph.D., M.A., R.N.
Nursing
Kings' College
London, UK

Nancy J. Norton
Consumer Representative/Advocate
President, International Foundation for Functional Gastrointestinal Disorders
Milwaukee, WI

Satish S.C. Rao, M.D., Ph.D.
American Gastroenterological Association
Georgia Regents University Medical Center
Augusta, GA

Todd H. Rockwood, Ph.D.
Health Services Research/Outcomes
University of Minnesota
Minneapolis, MN

Rebecca G. Rogers, M.D.
American College of Obstetrics and Gynecology

University of New Mexico
Albuquerque, NM

Vivian W. Sung, M.D., M.P.H.
Obstetrics and Gynecology
Alpert Medical School of Brown University
Providence, RI

Maureen White, M.S., M.D., M.B.A.
Blue Cross Blue Shield of Minnesota
Eagan, MN

Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

The list of Technical Experts who provided input to this report follows:

Adil E. Bharucha, M.B.B.S., M.D.
Gastroenterology
Mayo Clinic
Rochester, MN

Darla Bowen Cathcart, PT, DPT, CLT, WCS*
American Physical Therapy Association
University of Central Arkansas
Conway, AR

Tracy L. Hull, M.D.*
Colorectal Surgery
Cleveland Clinic Foundation
Cleveland, OH

Alayne D. Markland, D.O, M.Sc.*
Internal Medicine/Geriatric Medicine
University of Alabama
Birmingham, AL

Nancy J. Norton*
Consumer Representative/Advocate
President, International Foundation for Functional Gastrointestinal Disorders
Milwaukee, WI

Jane Potter, M.D., FACP
Internal Medicine
Nebraska Medical Center
Omaha, NE

Satish S.C. Rao, M.D., Ph.D.
American Gastroenterological Association
Georgia Regents University Medical Center
Augusta, GA

Todd H. Rockwood, Ph.D.*
Health Services Research/Outcomes
University of Minnesota
Minneapolis, MN

Rebecca G. Rogers, M.D.*
American College of Obstetrics and Gynecology
University of New Mexico
Albuquerque, NM

Vivian W. Sung, M.D., M.P.H.*
Obstetrics and Gynecology

Alpert Medical School of Brown University
Providence, RI

*Also provided comments on draft report.

Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

The list of Peer Reviewers follows:

Joshua I.S. Bleier, M.D.
Colon & Rectal Surgery
Pennsylvania Hospital
Philadelphia, PA

Dorothy B. Doughty, M.N., R.N., CWOCN, CFCN, FAAN
Deputy Editor, Journal of Wound Ostomy & Continence Nursing
Atlanta, GA

Patricia S. Goode, M.D., M.S.N.
Division of Gerontology, Geriatrics, and Palliative Care
University of Alabama at Birmingham
Birmingham/Atlanta VA Geriatric Research, Education, and Clinical Center
Birmingham, AL

Robert L. Yin, M.D., FACP
Gastroenterology
OSF St. Francis Hospital
Escanaba, MI

Treatments for Fecal Incontinence

Structured Abstract

Objective. To assess the efficacy and comparative effectiveness of surgical and nonsurgical treatments for fecal incontinence (FI) in adults.

Data sources. Ovid MEDLINE®, Embase®, PEDro®, CINAHL®, AMED, and the Cochrane Central Register of Controlled Trials (CENTRAL); hand searches of systematic reviews.

Methods. Two investigators screened abstracts of identified references for eligibility (examined treatments in adults with FI published from 1980 to the present that had a control/comparator group; case series were included for surgical interventions). Full-text articles were reviewed to identify patient-reported outcomes (FI episodes, FI severity, quality of life, urgency, pain, other). We extracted data, assessed risk of bias of individual studies, and evaluated strength of evidence for each comparison and outcome.

Results. Sixty-three unique studies met inclusion criteria; an additional 53 surgical case series were examined for adverse effects. Enrolled adults were mostly female with mixed FI etiologies. Most randomized controlled trials (RCTs) were nonsurgical (n = 38); 13 examined pelvic floor muscle training (PFMT) and PFMT with biofeedback (PFMT-BF). Meta-analysis was not possible because numerous outcomes were used. Low-strength evidence suggests that dietary fiber (psyllium) decreases FI episodes (-2.5 per week) at 1 month; clonidine has no effect; and PFMT-BF with electrostimulation is no more effective than PFMT-BF for FI severity and the FI Quality of Life scale (FIQL) over 2 to 3 months. Low-strength evidence at 6 months suggests that dextranomer anal bulking injections are more effective than sham injections on the FIQL, the number of FI-free days, and the percent of adults with at least 50-percent reduction from baseline in FI episodes, but no more effective than PFMT-BF with or without electrostimulation on FI severity (PFMT-BF -5.4 vs. dextranomer -4.6 point Vaizey score improvements) and the FIQL, and no more effective than sham injection on FI severity (-2.5 vs. -1.7 point sham improvement in Cleveland Clinic FI score [CCFIS]) or FI episode frequency. Moderate-strength evidence suggests that Durasphere® (off label) bulking injections reduce FI severity up to 6 months (-4 to -5 points CCFIS), but gains diminish thereafter. Evidence was insufficient for all other surgical and nonsurgical comparisons. Surgical improvements varied. Noninvasive nonsurgical treatments had few minor adverse effects (AEs). Surgical treatments were associated with more frequent and more severe complications than nonsurgical interventions. AEs were most frequent for the artificial bowel sphincter (22–100% of adults). Surgical AEs ranged from minor to major (infection, bowel obstruction, perforation, fistula). Major surgical complications often required reoperation; fewer required permanent colostomy. Only 12 percent of RCTs were high quality.

Conclusion. We found limited evidence to support any FI treatments beyond 3 to 6 months. Comparing the effectiveness of FI surgical and nonsurgical treatments is difficult because nonsurgical approaches generally precede surgery. Most current interventions show modest improvements in FI outcomes that meet minimal important differences (MIDs) in the short term, where MID is known. More invasive surgical procedures have substantial complications.

Numerous outcome measures and lack of compliance with study reporting standards are modifiable impediments in the field. Future studies should focus on longer term effects and attempt to identify subgroups of adults by FI etiology that might benefit from specific interventions.

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Introduction

Background

Fecal incontinence (FI) is the recurrent involuntary loss of feces,[1,2] which is defined by the frequency of episodes (such as daily or weekly episode counts) and by the consistency of the feces (solid, liquid, or mucus).[1,3] FI severity varies widely and the amount of leakage can vary across episodes. The negative psychological effects, social stigma, and reduced quality of life surrounding FI can be devastating.[3] Severe skin breakdown and ulceration can result from FI, particularly in nursing home residents and immobile adults.

FI prevalence increases with age and varies by sex, but prevalence estimates vary widely across patient populations and by the FI definition used. More recent terminology aimed at minimizing social stigma (accidental bowel leakage [ABL]), may further compound the discrepancies around FI prevalence estimates, because adults can have ABL (a symptom) for many reasons, not just FI (a chronic condition). Among community-dwelling adults, the prevalence of monthly bowel leakage is reported as 8.3 percent,[2] with slightly higher prevalence in women (9%) than men (7.7%).[2] FI affects less than 3 percent of young adults age 20 to 29 but more than 15 percent of adults age 70 and older.[2] Women over age 40 are disproportionately affected due to pelvic floor dysfunction after childbirth and obstetrical trauma. At least half of all nursing home residents and 83 percent of residents with severe cognitive impairment have experienced bowel leakage.[4] Approximately 3 percent of adults have FI at least weekly.[2] Among community-dwelling adults with at least monthly bowel leakage, 6.2 percent experience leakage as liquid stool, 1.6 percent as solid stool, and 3.1 percent as mucus.[2]

FI etiologies fall into two broad categories: non-neurological or neurological. Non-neurological causes of FI may be structural (e.g., muscle damage from episiotomy or surgery), functional (e.g., post-radiation or muscle atrophy), due to an underlying gastrointestinal (GI) disorder (e.g., inflammatory bowel disease), from stool consistency problems, or from other factors. Neurological causes of FI include damage to the nervous system or advanced cognitive impairment. Multiple causes of FI in individual adults are common and a dominant etiology may not be sought or determinable. Risk factors for FI include increasing age, female sex, chronic diarrhea, nerve damage (from injury, multiple sclerosis, or chronic diabetes), obstetrical trauma, postsurgical or postradiation complications, anal sphincter injury, cognitive impairment, or other factors such as severe constipation.[4,5]

Treatment goals are to decrease the frequency and severity of FI episodes. Treatments for FI are imperfect and are often delivered in combination. Most treatments are aimed at symptom reduction; few treatments, if any, afford long-term cures for FI. FI treatments typically follow a progression from nonsurgical to surgical, and from easy to implement (dietary fiber, drugs) to more intensive nonsurgical (pelvic floor muscle training with biofeedback [PFMT-BF]), to more invasive nonsurgical (anal sphincter tissue bulking injections) or surgical treatments. However, nonsurgical treatments may also be used to complement surgical treatment. As a result, the nature of patients offered different types of FI treatment can vary widely.

Nonsurgical treatments include dietary fiber supplementation,[5] bowel schedules, stool-modifying drugs,[6] PFMT-BF,[7,8] anal plugs,[9,10] rectal irrigation,[10,11] or combinations thereof.[5,7] A new vaginal bowel control device received Food and Drug Administration (FDA) approval in February 2015,[12] and other interventions, such as percutaneous posterior tibial nerve stimulation are emerging. Injections of biocompatible tissue-bulking agents into the anal canal walls are a newer, more invasive nonsurgical procedure.[13] Surgical procedures used to treat FI in the United

States include implanted sacral nerve stimulation (SNS), radiofrequency anal sphincter remodeling (SECCA), antegrade colonic enema (ACE), anal sphincter repair (sphincteroplasty), sphincter replacement (artificial anal sphincter), surgical correction of conditions that can result in FI (rectal prolapse, hemorrhoids, or rectocele), or, when all other treatments fail, colostomy.[1,5,14,15]

FI etiologies and other patient factors dictate feasible treatment options.[1] For example, the range of treatment approaches used for FI in adults with spinal cord (neurologic) injury would differ from those used to treat pelvic floor muscle atrophy (weakness) or anal sphincter injury. However, etiologic differentiation can be clinically challenging.

Although many recent systematic reviews have assessed the effectiveness of component treatments for FI,[6-9,13-22] none has yet examined the collective evidence for FI treatment effectiveness, reported overall treatment effects and those within subgroups of adults defined by their FI etiologies (when available), or examined the long-term treatment effects across all FI treatments. Given the heterogeneous population of adults afflicted with FI, information on subgroup treatment outcomes across that range of available FI treatments would advance knowledge and possibly improve patient care and outcomes.[3]

This systematic review synthesizes the available evidence on FI treatment outcomes across FI etiologies and treatments to provide current and potentially better information to aid decisionmaking for both patients and physicians and identifies gaps in the evidence base for treatment-subgroup combinations. When possible, we addressed additional information on baseline patient factors that could modify treatment effects, such as age, sex, FI severity, comorbidities, and prior FI treatments.

Our findings should inform FI treatment guidelines and clinical decisions in general.

Scope and Key Questions

Scope of the Review

This review provides comparative effectiveness (benefits and harms) information on FI treatments for patients and their health care providers. We report this information in the context of how FI treatment decisions are commonly made along the spectrum of available interventions, from initial presentation to a primary care provider, to more complex and invasive interventions for persistent and/or severe FI. Adults with FI are rarely offered surgery as an initial approach; even with structural injuries, such as anal sphincter tears, the magnitude of structural defect may not dictate the functional improvements possible from conservative measures alone. Therefore, nonsurgical interventions are often the first-line treatment, and these measures are often continued throughout successive additional treatments if the desired level of fecal continence is not obtained, or sustained, with initial measures.

We report treatments from least to most invasive within each category of nonsurgical and surgical approaches. We report summary information across all included etiologies, then add etiologic subgroup-specific outcomes whenever the literature permitted.

The analytic framework for this review is in Appendix A. The PICOTS elements (Population, Intervention, Comparator, Outcomes, Timing and Setting) that determined study inclusion are identified in the Methods section.

Key Questions

We synthesized the evidence from the published literature to address two Key Questions (KQ):

KQ 1: What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of fecal incontinence in affected adults?

KQ 2: What adverse effects are associated with specific treatments for adults with fecal incontinence?

Methods

The methods for this comparative effectiveness review (CER) follow the methods suggested in the AHRQ "Methods Guide for Effectiveness and Comparative Effectiveness Reviews" (available at www.effectivehealthcare.ahrq.gov); some methods map to the PRISMA checklist.[23] The topic and Key Questions underwent initial refinement through conversations with Key Informants, and through a public posting process. We subsequently recruited a technical expert panel (TEP) to provide specialized content feedback on the systematic review protocol, which is posted on AHRQ's Effective Healthcare Web site. This section summarizes the methods we used.

Literature Search Strategy

Bibliographic database searches identified RCTs and observational studies published from 1980 to June 2015 on treatments for adults with FI to include early studies of antidiarrheal drugs that are currently used in the treatment of FI. Relevant bibliographic databases for this topic included Ovid MEDLINE®, Embase®, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL), Ovid Physiotherapy Evidence Database (PEDro) ®, and Allied and Complementary Medicine (AMED). Our search strategies are shown in Appendix B. An experienced librarian developed the MEDLINE search strategy, which was modified for other databases. Additionally, we searched reference lists of systematic reviews published since 2007 that evaluated treatments for FI to confirm that our search captured evidence in recent review updates and to avoid the inclusion of obsolete treatments or interventions that have been replaced with newer approaches.

Grey literature searches for unpublished research information from government or industry were conducted via ClinicalTrials.gov and from Scientific Information Packets (SIP) received from relevant industry stakeholders who submitted published and unpublished information on their product(s) at the request of AHRQ for this review. Grey literature search results were used to identify studies and outcomes not reported in the published literature to assess publication and reporting bias and inform future research needs.

Studies for this comparative effectiveness review of treatments for FI were selected based on the PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting) framework and on the study-specific inclusion criteria described in Table 1.

Table 1. Study inclusion criteria for fecal incontinence review

Category	Criteria for Study Inclusion
PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting)	• Population o Adults age 18 and older with patient- or investigator-reported FI. Included adults per study were classified by FI etiologic subgroups or special population: mixed, obstetric, geriatric (special population), structural, GI (altered GI motility/stool texture), neurogenic (SCI vs. mixed neurogenic), unknown or not reported. Additional subgroups were included as identified in the literature. o Excluded: Adults with fistulas; adults with structural problems (e.g., rectal prolapse) that may or may not be associated with FI for which the treatment was designed to correct the structural problem, not treat FI. Studies of adults with flatal (without fecal) incontinence were excluded. • Interventions o Studies that tested the effectiveness FDA-approved treatments for FI and medications used off-label (not specifically approved for the treatment of FI) and available for use in the U.S. Nonsurgical, surgical, and combinations of interventions were included for KQ 1 and KQ 2. o For treatments not FDA-approved but used outside of the U.S., studies were included if

Category	Criteria for Study Inclusion
	a treatment was FDA-approved for some indication and was used off-label in the U.S. and if a device was FDA-approved for FI under a certain brand name (e.g., an anal plug) and there were studies comparing it with other brands approved only in Europe. o Excluded: We excluded colostomy, diarrhea treatments in the absence of FI, laxatives used exclusively for stool impaction and non-FDA approved treatments (TOPAS pelvic floor repair system; magnetic anal sphincter; dynamic (stimulated) graciloplasty; tissue-bulking injections with non-FDA approved agents; other non-FDA approved drugs). • Comparators o All other treatment options, alone or in combination. Where available, trials with placebo or sham controls were included. • Outcomes: Studies reported at least one patient-reported outcome o **KQ 1**: Benefits of treatment ▪ FI Severity and Impact: Changes from baseline (such as FI frequency, FI consistency, CCFIS,[24] FISI,[25] Vaizey FI Score,[26] Pescatori FI Score,[27] SMFIS,[28] fecal urgency, change in FI coping behaviors, emotional and psychological outcomes, social activity, and sexual function) ▪ Quality of Life: such as the FIQL Scale[29] ▪ Health status: such as SF-36[30] ▪ Other: satisfaction with treatment, effectiveness of treatment, improvement o **KQ 2**: Adverse effects of treatment(s): Pain (abdominal, other); worsening of FI (frequency, severity); GI symptoms (such as cramping, bloating, difficultly evacuating bowels, constipation); surgical complications (such as infection, the need for revision surgery or other surgery (e.g., colostomy); negative emotional/psychological effects; other adverse effect(s) related to treatment (local dermatitis, skin breakdown, urinary tract infection, headache, nausea etc.) • Timing o Followup more than 1 day. Since FI is a chronic condition, most interest is in studies with at least 3 months of followup after treatment initiation were the main focus of the review o Excluded: Studies where the only outcome was assessed the same day as the only treatment • Setting o Any setting (community dwelling, long-term care, other)
Study designs	• RCTs, nonrandomized controlled trials, and prospective or retrospective cohort studies with control groups were included. Surgical observational studies without control groups (case series, n >10) were included if they assessed treatment harms (KQ 2). Published systematic reviews were used for reference list cross checking only.
Time of publication	• English language RCTs and observational studies published from 1980 forward (to include early studies of drugs that are currently used in the treatment of FI); reference lists from systematic literature reviews were examined from 2007 forward.
Language of publication	• We limited included studies to English language publications because that literature best represents FDA-approved and/or interventions available in the United States. The search strategies were not limited by language.
Study quality	• All studies that met the inclusion criteria were screened for eligibility • Studies that did not adequately report study information to allow the abstraction of patient-important outcomes identified in the Key Questions, or had indeterminate numerators and denominators for those outcomes and adverse event rates were excluded from the analytic set.

CCFIS = Cleveland Clinic Fecal Incontinence Score; FDA = Food and Drug Administration; FI = Fecal Incontinence; FIQL = Fecal Incontinence Quality of Life Instrument; FISI = Fecal Incontinence Severity Index; GI = gastrointestinal; KQ = Key Question; RCT = randomized controlled trial; SMFIS = St. Mark's Fecal Incontinence Score; SF-36 = Medical Outcomes Study Short-Form 36-item Health Survey; SCI = spinal cord injury; PICOTS = Population, Intervention, Comparator, Outcomes, Timing, Setting

Study Selection and Data Extraction

Two independent investigators reviewed titles and abstracts of bibliographic database search results to identify studies that examined interventions for FI and reported at least one patient-reported outcome regarding FI severity, impact, or quality of life. Citations deemed potentially

eligible by either investigator underwent full text screening to determine if all inclusion criteria were met. Differences in screening decisions were resolved by consultation between investigators and a third investigator. Studies excluded during full-text screening are listed in Appendix C.

We extracted data from included studies into evidence tables by the type of study design. Extracted data included the relevant population, intervention, baseline, and outcomes data on the adult subgroups of interest. Initial data abstraction was quality checked by a second investigator.

Quality (Risk of Bias) Assessment of Individual Studies

Risk of bias of eligible studies was assessed by at least two independent investigators using instruments specific to each study design (Appendix D). Two investigators consulted to reconcile discrepancies in overall risk-of-bias assessments and, when needed, a third investigator was consulted to reconcile the summary judgment. We assessed RCT risk of bias using a modified Cochrane risk-of-bias tool[31] (Appendix D). The risk of bias elements of the tool are sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias (i.e., problems not covered by other domains).[31] We developed an instrument to assess risk of bias for observational studies using the RTI Observational Studies Risk of Bias and Precision Item Bank[32] (Appendix D).We selected items most relevant in assessing risk of bias from studies of FI treatments, including subject selection, baseline patient information, attrition, ascertainment of outcomes and analytic tools used to address selection bias in nonrandomized studies. An overall summary risk-of-bias assessment for each study was classified as low, moderate, or high based on the collective risk of bias inherent in each outcome domain and our confidence that the results were believable given the study's limitations.[33] When the two investigators disagreed, a third trained investigator was consulted to reconcile the summary judgment.

Data Synthesis

For each Key Question, we summarized the results into evidence tables and qualitatively synthesized evidence by the type of study (RCT, observational, case series) for each treatment comparison and outcome combination within specific followup periods. Studies were grouped by intervention category and then etiologic subgroup. Pooling was planned for measures that assessed the same outcome and had comparable scoring characteristics.

We emphasized patient-centered outcomes in this review. The primary outcomes were FI severity[25] including episode frequency and the type and amount of leakage (Appendix E), and FI quality of life,[29] as identified in the literature and by Key Informants (consumers, clinical experts, and researchers).[34] The FI severity measures are summarized in Table 1 above, and in Appendix E, which includes details of common FI outcomes measures and minimal clinically important differences, if known.

We had planned to pool data, but pooling was not possible due to heterogeneous treatments and numerous and varied outcome measures that were not comparable on scoring (Appendix F, Table F1). Rather, we summarized evidence qualitatively with as much etiologic information as was feasible. In general, RCTs were given priority over observational studies with comparators when risk of bias was low or moderate; high risk of bias studies of either design provided low value information. Case series were used only for postsurgical harms because the harms were unlikely to occur under other circumstances. We report treatment effects using change scores from baseline, when reported.

Strength of the Body of Evidence

We evaluated the overall strength of evidence for selected intervention-outcome pairs based on five domains:[35] (1) study limitations (internal validity); (2) directness (single direct link between the intervention and outcome); (3) consistency (similarity of effect direction and size); (4) precision (degree of certainty around an estimate), with the study limitations domain having considerable importance; and (5) reporting bias, which was evaluated by the potential for bias related to publication, selective outcome reporting, or selective analysis reporting by comparing reported results with those in the methods sections and an assessment of the grey literature to assess potentially unpublished studies. Study limitations were rated as low, moderate, or high according to study design and conduct. Consistency was rated as consistent, inconsistent, or unknown/not applicable (e.g., single study). Directness was rated as direct or indirect. Precision was rated as precise or imprecise. Reporting bias was rated as detected or not detected. Deficiencies in domains lowered the strength of evidence grade.[35] We required at least two moderate risk of bias studies or one sufficiently powered, low risk of bias RCT to assign a low strength of evidence rather than considering it to be insufficient. Moderate or high strength of evidence ratings were based on risk of bias and additional strength of evidence domain criteria. We required at least two low risk of bias studies for moderate strength of evidence, and two sufficiently-powered low risk of bias studies for high strength of evidence, plus intervention-outcome pairs needed a positive response on two out of the three domains other than risk of bias. We graded strength of evidence for treatment-patient-reported outcome combinations that assessed FI severity/impact or quality of life in studies with low or moderate risk of bias as per the above criteria. Based on these factors, the possible strength of evidence (SOE) grades[35] were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change the estimates.
- Moderate: Moderate confidence that the estimate reflects the true effect. Further research may change estimates and our confidence in the estimates.
- Low: Limited confidence that the estimate of effect lies close to the true effect. Further research is likely to change the confidence in the effect estimate or change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

Applicability

Applicability of studies was determined according to the PICOTS framework. Study characteristics that affected applicability included, but were not limited to, enrollment of adults with heterogeneous etiologic factors, narrow (or excessively broad) inclusion criteria, or patient and intervention characteristics that differed from those described by population studies of FI interventions. All treatments are not feasible for all FI etiologies at all time points (newly diagnosed or with longstanding FI), so sample differentiation and prior treatments are important. Adults in clinical trials of FI treatments may have higher function, be younger, or be less impaired than the FI patient population as a whole. Some comparator interventions are only available outside of the United States and may never be considered for use in the United States. Short followup on interventions may be less applicable to the long-term management of chronic FI for patients and providers.

Peer Review and Public Commentary

Experts in gastroenterology, colon and rectal surgery, urogynecology, internal medicine, geriatrics, and nursing, and individuals representing stakeholder and user communities, were invited to provide external peer review of this report; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comments. We subsequently addressed all reviewer comments, revised the report as appropriate, and documented the comments and our responses in a disposition of comments table that will be available 3 months after AHRQ posts the final systematic review on their Effective Health Care Web site.

Results

Overview

This section is organized by type of treatment, following the general sequence of treatments as they occur in clinical practice, from nonsurgical (least to more invasive) to surgical. We planned to organize this section by etiologic subgroups, but that proved impossible because in most articles, FI etiologies were mixed and FI etiologies were inconsistently defined and reported, as is consistent with clinical difficulties in determining etiologic attribution in FI. Summary statements about the included studies are below; individual study details can be found in the report tables and appendices.

Results of Literature Searches

We identified 2,978 unique citations (Figure 1) from all databases combined. We examined the full text of 192 articles to determine final inclusion. Of those, 117 studies were included in the review: 50 RCTs, 14 observational studies (OBS) with comparators, and 53 surgical case series. Thirty-eight randomized controlled trials (76%) assessed nonsurgical treatments; 12 assessed surgical interventions including sacral nerve stimulation. We found RCT evidence for one off-label tissue bulking agent (Durasphere®) that was not on our initial list of treatments.

Due to variability in followup assessment timing, we considered outcomes evidence as short-term (less than 3 months), intermediate-term (3 to 6 months) or long-term (more than 6 months), (Appendix F, Table F2). Evidence tables in this report (Tables 2-17) and Appendix F provide detailed information about the included studies.

Evidence of publication bias was identified from the information we reviewed in Scientific Information Packets received from industry, and by examining clinicaltrials.gov.

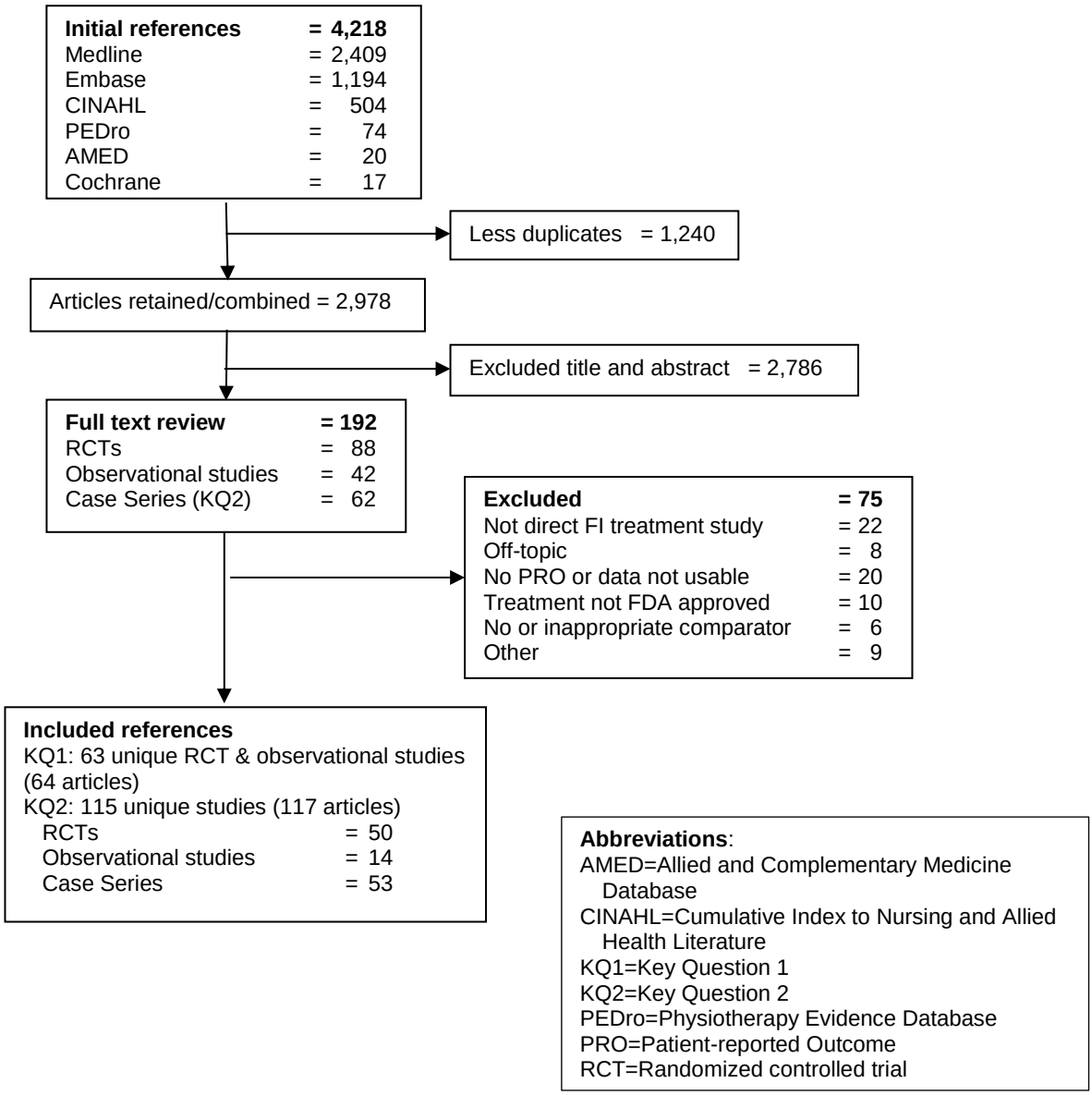
KQ 1: What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of fecal incontinence in affected adults?

Included studies are listed under Nonsurgical or Surgical headings below, and listed by the type of intervention in the approximate order that they might be used in clinical practice. We did not find RCT or OBS with comparison groups for anal plugs, antegrade colonic irrigation (ACE), or radiofrequency anal sphincter remodeling (SECCA).

Nearly two-thirds (62%) of RCTs enrolled adults with mixed FI etiologies, while 20 percent of RCTs did not report FI etiology (Appendix F, Table F3). FI severity at baseline was inconsistently reported and varied widely per study inclusion criteria.

The mean age of enrolled adults was 55 to 65 years in 62 percent of 37 nonsurgical RCTs that reported age, and 75 percent of surgical RCTs. Females comprised 81 percent of enrolled adults in 35 nonsurgical RCTs (Tables 2-17) and 95 percent of adults in 11 surgical RCTs (Appendix F, Table F4) that reported patient sex, but these proportions varied by FI etiology and type of intervention.

Figure 1. Disposition of fecal incontinence studies identified for this review



Nonsurgical Treatments

Key Points

- Low-strength evidence suggests that dietary fiber supplementation with psyllium decreases FI frequency by 2.5 occurrences per week after 1 month of use; clonidine has no effect; and PFMT-BF with electrostimulation is no more effective than PFMT-BF on FI severity and the FI Quality of Life Scale (FIQL) scores over 2 to 3 months.
- Low-strength evidence at 6 months suggests that dextranomer tissue-bulking injections are more effective than sham injections on the FIQL, number of FI-free days, and percent of adults with at least 50 percent reduction from baseline in FI episodes; no more

- effective than PFMT-BF with or without electrostimulation on FI severity (PFMT-BF -5.4 versus dextranomer -4.6 point Vaizey improvements) and FIQL; and no more effective than sham injection on FI severity (-2.5 versus -1.7 point sham CCFIS improvement) or FI episode frequency. (See Appendix E for FI outcome measures)
- Moderate-strength evidence suggests that Durasphere® (off-label) bulking injections reduce FI severity (-4 to -5 points in CCFIS) up to 6 months, but gains diminish thereafter.
- Evidence is insufficient for PFMT-BF versus standard care (such as dietary fiber and stool-modifying drugs); all other PFMT studies assessed refinements in treatment delivery by comparing PFMT to another variation of PFMT.
- Evidence was insufficient for all other nonsurgical interventions.
- In most cases, short-term outcomes improvements in both treated and active controls met minimum clinically important differences (MID) when those values were known (usually 2 to 6 points, various scales, Appendix E); studies that claimed greater improvements typically excluded nonresponders, noncompleters, or those not fully compliant with study protocols.
- The wide range of outcome measures limited comparability across studies.
- Most nonsurgical RCTs (84%) had moderate or high risk of bias.
- Incomplete reporting of baseline patient information and FI etiologies was common.
- Most evidence was short term (Appendix F, Table F2).

Dietary Fiber

The evidence for dietary fiber and fiber supplementation in FI is exclusively short term (up to 3 months (Table 2). Two RCTs[36,37] assessed the 31 day and 38 day effects of various dietary fiber supplements on FI frequency, and stool frequency and consistency. Low-strength evidence[36] suggests that dietary fiber supplementation with psyllium reduces FI frequency by 2.5 occurrences per week and has no effect on FI quality of life as measured with the FIQL.[36]

Evidence was insufficient for other outcomes, including one moderate risk of bias RCT that found no added benefit of dietary fiber in addition to loperamide on FI severity and the FIQL over 3 months[38] (Table 2). Evidence was insufficient for methylcellulose plus loperamide versus no treatment[39] (Appendix F, Table F5).

Pharmacological Treatments

Drug studies were exclusively short term (1 to 6 weeks) and most were 1 month in duration. The effectiveness of oral and topical medications for FI was examined in 11 RCTs: three of topical phenylephrine versus placebo[40-42] (Table 3), four of antidiarrheal medications[43-46] (three versus placebo, one with active comparators, Table 4), and four studies of other medications[47-50] (all versus placebo, Table 5). Low-strength evidence suggests that oral clonidine has no effect on FI severity as measured with the FI and Constipation Assessment (FICA).[47] Evidence was insufficient for loperamide,[43-46] topical phenylephrine (10%[41,42] and 30%[40]), zinc-aluminum ointment,[48] estrogen cream,[49] and valproate sodium.[50]

Pelvic Floor Muscle Training and Adjunctive Modalities

Pelvic floor muscle training using biofeedback (PFMT-BF) was the most frequently studied intervention in the literature we reviewed; 16 studies (13 RCTs and 3 OBS[51-53]) assessed the effects of PFMT-BF with or without electrostimulation on the outcomes of FI frequency and

severity, quality of life (general and FI-specific, the FIQL), and perceived improvement (Tables 6-12 and Appendix F, Table F5).

We found insufficient evidence for PFMT-BF versus standard care (such as dietary fiber, stool-modifying drugs, and/or advice, Table 6 and Appendix F, Table F5). The definition of *standard care* varied across studies. Only two RCTs[54,55] (Table 6) with moderate[55] and high[54] risk of bias assessed the benefit of PFMT-BF versus standard care, and one high risk of bias observational study[53] (Appendix F, Table F5) examined PFMT-BF plus standard care versus standard care alone. Most of the literature focused on ways to improve or prolong the purported benefits of PFMT for FI by comparing PFMT to another variation of PFMT,[56-66] rather than to establish the benefits of it. Only two RCTs used PFMT alone as a control[56,57] (Table 7); all other studies (Tables 8-12) assessed refinements in PFMT delivery by testing one form of PFMT against another, including PFMT plus FI education[58] (Table 8), biofeedback sensor comparisons[59,60] (Table 9), exercise comparisons[61] (Table 10), electrostimulation frequency comparisons[62,63] (Table 11), electrostimulation to augment PFMT-BF[64-66] (Table 12), or examined the mode of training delivery (by phone or in-person) on outcomes[51] (Appendix F, Table F5). Risk of bias was moderate to high in all PFMT studies.

We found low-strength evidence that PFMT-BF with electrostimulation is no more effective than PFMT-BF on FI severity and FI quality of life (FIQL).[65,66] Evidence was insufficient for all other PFMT comparisons.[51,52,56-64]

PFMT-BF was associated with improvements in FI outcomes (usually 2 to 6 points, various scales) in most studies, but improvements did not differ significantly from those of the comparison group. Most PFMT RCTs reported 3 to 6 month outcomes (Appendix F, Table F2); only four studies reported outcomes for randomized patients beyond 6 months.[55,57,61,63]

Anal Electrostimulation

Evidence was insufficient for home-based anal electrostimulation without PFMT versus home-based sham stimulation on symptoms and FI severity,[67] and for home-based electrostimulation versus hospital-based therapy[68] in the short term (Table 13). The extremely low compliance with home-based electrostimulation in one RCT[67] (only 25 percent of the treatment group used the stimulator at least 20 of the 34 protocol-recommended hours) suggests that home-based stimulator use for FI may not be an acceptable option to patients, even if it worked.

Rectal Irrigation

Evidence was insufficient for rectal irrigation versus a non-FDA approved injectable bulking agent for mixed FI etiologies from one study[69] (Appendix F, Table F5).

Mixed Nonsurgical Interventions

Mixed interventions were primarily assessed for two groups of adults: older adults residing in nursing homes and adults with spinal cord injuries (SCI). Both groups may deal with FI, constipation, or both. The goal of bowel management is to minimize extremes and maintain bowel regularity.

Two RCTs focused on bowel management interventions for adults with SCI[70,71](Table 14). Females comprised 31 percent of enrolled adults; the overall median age was 48 years. One moderate risk of bias study found that transanal irrigation improved bowel and FI outcomes more

than supportive, guidelines-based care over 10 weeks.[70] One high risk of bias study reported that a 6-week step-wise, increasing intensity bowel management program worsened FI outcome.[71]

In contrast, two high risk of bias RCTs assessed staff-directed interventions for FI and bowel issues in nursing home residents with mixed results (Table 15). Females comprised 83 percent of enrolled residents; the overall mean age was 87 years. Both interventions focused on multiple factors affecting bowel regularity, including aspects of diet, fluids, activity, and care. One RCT found significant reductions in FI frequency with prompted toileting four times per day, exercise and increased fluid offering 5 days per week.[72] The other RCT was a multicomponent intervention for UI and FI, which did not affect FI frequency.[73]

Posterior Tibial Nerve Stimulation

Percutaneous posterior tibial nerve stimulation (PTNS) is not FDA approved for FI but is currently being studied as a nonoperative off-label treatment option, especially prior to considering permanent SNS (www.clinicaltrials.gov). One small, moderate risk of bias RCT (Table 16) examined the effects of PTNS versus SNS on FI episodes and the CCFIS.[74] The evidence for PTNS is insufficient.

Anal Sphincter Tissue-Bulking Injections

Four low risk of bias RCTs (Table 17) examined anal sphincter tissue-bulking injections: two RCTs of dextranomer,[75,76] which is FDA-approved for FI, and two of an off-label injectable, Durasphere®[77,78] (FDA-approved for urethral bulking for urinary incontinence).

Low-strength evidence at 6 months post-treatment suggests that dextranomer tissue-bulking injections are no more effective than PFMT-BF with or without electrostimulation on FI severity and FI-related quality of life as measured by the FIQL.[75]

Low-strength evidence at 6 months post-treatment suggests that dextranomer tissue-bulking injections are more effective than sham injections on FI quality of life (FIQL scale), the number of FI-free days, and in reducing FI episodes 50 percent or more from baseline over 6 months, but no more effective than sham injection on FI severity (CCFIS) and FI episode frequency.[76]

Durasphere® (off-label) anal sphincter injections improved FI severity (CCFIS) by several points shortly after injections, but gains diminished slightly between 6 months and 1 year.[77,78] Both studies used a non-FDA approved comparator (PTQ™).

Table 2. KQ 1. Randomized controlled trial evidence for dietary fiber and dietary fiber supplementation for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Bliss, 2014[36] *Bliss, 2011[79] used same sample as Bliss, 2014[36], minus 17*	Compare fiber supplements	N=206 n=206 74% F; 58 y Not reported T: 38 d. FU: 38 d.	T_1: carboxymethy-cellulose (CMC) (53) T_2: gum arabic (50) T_3: psyllium (54) C: placebo (49)	**FI frequency/wk**, amount, consistency, severity; FIQL	FI significantly decreased by 2.5 episodes per week with psyllium (vs. placebo) and increased 1.5 episodes per week with CMC. No differences in other outcomes. Sufficient power.	Low
Bliss, 2001[37]	Compare fiber supplements	N=39 n=39 79% F; 61 y Not reported T: 31 d. FU: 31 d.	T_1: psyllium (13) T_2: gum arabic (13) C: placebo (13)	% incontinent, stool frequency, stool consistency, dietary intake	Tested between-group comparison at followup. Proportion of incontinent stools decreased most with gum arabic (48%) and psyllium (32%). No change in stool freq. Power not reported.	Moderate
Lauti, 2008[38]	Does fiber supplement and loperamide improve FI over low residue diet and loperamide	N: 63 n: 47 91% F; 59 y Mixed T: 12 wk (6 + 6) FU: 6 wk, 12 wk	Crossover T: balanced fiber diet + fiber supplement + loperamide (32) C: low residue diet + placebo fiber + loperamide (31)	**FISI**, FIQL	Both groups improved. No significant difference in FISI improvement between treated vs. control (-13 vs. -12.4). FIQL largely unchanged. Sufficient power.	Moderate

C = Comparator/control; CMC = carboxymethy-cellulose; d = day; F = female; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FISI = Fecal Incontinence Severity Index; FU = Follow up T_1 = Treatment group 1 T_2 = Treatment group 2 T_3 = Treatment group 3; wk = week; y = years

[a]Significant = statistically significant

Table 3. KQ 1. Randomized controlled trial evidence for topical phenylephrine (sphincter function enhancement drug) for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Park, 2007[40]	Efficacy of 30% phenylephrine gel for FI after low anterior resection for rectal cancer	N=35 n=29 37% F; 60 y Postsurgical T: 4 wk FU: 4 wk	T: 30% topical phenylephrine (17) 2x/day C: placebo 2x/d (12)	FISI, FIQL, Global Efficacy	Phenylephrine did not improve FISI or FIQL scores. Subjective improvement in 29% treated (33% controls). Power not reported. Excluded post-randomization data from those with *poor compliance*.	High
Carapeti, 2000[41]	Effectiveness of 10% topical phenylephrine in FI patients with IAS dysfunction	N=36 n=36 61% F; 58 y Not reported T: 4 wk each FU: 4 wk, 8 wk	Crossover, 1 wk. washout T: topical 10% phenylephrine gel (anus) 2x/d (36) C: placebo gel (36)	**Vaizey score**, subjective improvement	Vaizey improved 2 to 2.9 points from baseline, regardless of treatment period. No significant difference in mean improvement in Vaizey or subjective improvement in treated vs. placebo period by group. Sufficient study power.	Moderate
Carapeti, 2000[42]	Effectiveness of 10% topical phenylephrine in FI patients with ileoanal pouch	N=12 n=12 58% F; 44 y Ileoanal pouch T: 4 wk each FU: 4 wk, 8 wk	Crossover, 1wk. washout T: topical 10% phenylephrine gel (anus) 2x/d (12) C: placebo gel (12)	Vaizey score, overall FI symptom score, self-rated improvement	Results reported for period 1 only due to significant treatment x period interaction. Significant improvement in mean Vaizey in treated vs. controls (6 vs. 0 points). FI symptoms lower when treated. Study likely underpowered.	High

C = Comparator/control; F = female; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FISI = Fecal Incontinence Severity Index; FU = Followup; IAS = internal anal sphincter; T = Treatment group; Vaizey = Vaizey Fecal Incontinence score; wk = week; y = year

[a]Significant = statistically significant

Table 4. KQ 1. Randomized controlled trial evidence for antidiarrheal drugs for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Sun, 1997[43]	Effectiveness of loperamide oxide for chronic diarrhea with FI	N=11 n=11 73% F; 56 y Mixed T: 1 wk each FU: 2 wk, 4 wk	Crossover, 1wk run-in, washout T: loperamide 8mg/d (11) C: placebo (11)	FI episodes, % fully continent, stool frequency/consistency, urgency, FI severity, urgency, diarrhea, abdominal pain	Significantly more treated vs. placebo achieved continence and no diarrhea (65% vs. 27%), and had significant reduction urgency and stool frequency. Power not reported.	High
Hallgren, 1994[44]	Effectiveness of loperamide HCl after proctoco-lectomy for ulcerative colitis	N=30 n=28 27% F; 38y Postsurgical T: 8 d each FU: 15 d, 30 d	Crossover, 1wk run-in, washout T: loperamide HCl 12mg/d (30) C: placebo (30)	Defecation frequency, need for night evacuation, soling daytime, soiling nighttime, use of pads, flatus release	Tested differences in outcome at followup; no baseline outcomes reported. Loperamide significantly decreased FI and pad use over placebo; no change in defecation frequency. Power not reported.	Moderate
Read, 1982[45]	Effectiveness of loperamide for chronic diarrhea with FI and urgency	N=26 n=26 57% F; 45 y Mixed T: 1 wk each FU: 1 wk, 2 wk	Crossover, washout not reported T: loperamide 12mg/d (26) C: placebo (26)	FI episodes/wk; stool frequency, weight and consistency; urgency; improvement in FI and urgency	Tested differences in outcome at followup. Loperamide significantly decreased FI and urgency episodes, stool frequency and related outcomes over placebo; more reported improvement on drug. Power not reported.	Moderate
Palmer, 1980[46]	Compare 3 drugs for chronic diarrhea (95% had urgency with FI)	N=30 n=25 % F NR; age NR Mixed T: 4 wk each FU: outcomes every 4 wk up to 12 wk	Crossover; used 3 wk data per period T_1: loperamide HCl 2mg/d (30) T_2: codeine phosphate 45mg/d (30) T_3: diphenoxylate 5mg/d (30)	FI episodes, # of patients with FI, stool freq. and consistency, urgency episodes, dose/capsule consumption	Baseline data for urgency only. Not all outcomes were reported. Loperamide and codeine decreased number of patients with urgency more than diphenoxylate; all drugs decreased stool frequency. Power not reported. Analyzed completers only.	High

C = Comparator/control; d = day; F = female; FI = Fecal incontinence; FU = Followup; HCl = Hydrochloride; mg = milligrams; T = Treatment group; T_1 = Treatment group 1 T_2 = Treatment group 2 T_3 = Treatment group 3; wk = week; y = year

[a]Significant = statistically significant

Table 5. KQ 1. Randomized controlled trial evidence for other drugs for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; FI Etiology; % Female; Mean Age; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Bharucha, 2014[47]	Effectiveness of clonidine vs. placebo in women with FI	N=44 n=44 100% F; 58 y Mixed T: 4 wk FU: 4 wk	T: Clonidine 0.2mg/d (22) C: placebo (22)	**FICA**, FI count, days of FI, FIQL, FISI, satisfaction, rectal urgency, loperamide use	No significant difference between groups in FICA improvement (1.6 clonidine vs. 1.5 placebo) or other outcomes. Sufficient power.	Low
Pinedo, 2012[48]	Compare Zinc-Aluminum ointment to anal submucosa vs. placebo for FI	N=50 n=44 % F NR; 61 y Not reported T: 1 mo FU: 1 mo	T: Zinc-aluminum ointment 3x/d (25) C:placebo (25)	**CCFIS**, FIQL	Significant CCFIS between-group improvement from baseline in treated vs. controls (-8.1 vs. -3.6), and all FIQL subscales. Underpowered study. Analyzed completers only.	Moderate
Pinedo, 2009[49]	Compare topical estrogen vs. placebo for FI in postmenopausal women	N=36 n=35 100% F; 69 y Not reported T: 3x/d for 6 wk FU: 6 wk	T: Estrogen cream to anal submucosa (18) C: placebo (18)	**CCFIS,** FIQL	Both groups improved in CCFIS (-5 treated, -3 controls); between-group test not significant. Within-group FIQL improvements minimal in both groups. Sufficient study power.	Moderate
Kusunoki, 1990[50]	Effectiveness of valproate sodium for FI after ileoanal anastomosis	N=17 n=17 24% F; 34 y Postsurgical T: 1 wk FU: 1 wk	Crossover, 3 d. washout T: Valproate sodium 1600mg/d (17) C: placebo (17)	FI count (soiling), stool frequency., perianal skin trouble	Tested within-group changes only: Greater reduction in FI soiling (9 vs. 2) and mean stool frequency. (4 vs. 0.4) during treatment vs. placebo period. Power not reported.	Moderate

C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; F = female; FI = Fecal incontinence; FICA = Fecal Incontinence and Continence Assessment; FIQL = Fecal Incontinence Quality of Life scale; FISI = Fecal Incontinence Severity Index; FU = Followup; mo = month; mg = milligrams; T = Treatment group; wk = week; y = year

[a]Significant = statistically significant

Table 6. KQ 1. Randomized controlled trial evidence for pelvic floor muscle training with biofeedback (PFMT-BF) versus standard care

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Damon, 2014[54]	Does PFMT-BF plus *standard care* improve FI outcomes over standard care only?	N=157 n=92-142 varied 77% F; 61 y Mixed T: 4 mo. FU: 4 mo.	T: PFMT-BF (20 sessions) plus standard care (77) C: standard care= laxative, oral bulking agent, loperamide (80)	**Treatment effectiveness** (-5 to 5), CCFIS, FIQL, KESS, SF-12, symptom change	Differences between groups in opinion of treatment effectiveness, symptom change, CCFIS, KESS, FIQL, or SF-12 were not significant. Underpowered study. Analyzed completers only.	High
Norton, 2003[55]	Does biofeedback (PFMT-BF, various modes) improve FI over *standard care* (advice on diet, drugs, bowel evacuation)	N=171 n=171 (ITT) 93% F; 56 y Mixed T: 3-6 mo. FU:6 mo., 1yr	T_1: Hospital and home-based PFMT-BF plus advice (42) T_2: Hospital-based PFMT-BF plus advice (49) T_3: PFMT with DRF plus advice (43) C: standard care=advice (37)	**Treatment effectiveness and rating thereof,** Vaizey, Bowel Symptom Questionnaire, SF-36, FI counts/wk), HAD, quality of life (FI-unpublished)	Over half of patients improved; biofeedback was no better than standard care with advice. No differences between groups in functional outcomes. Quality of life, SF- 36, (vitality, mental, social) and HAD significantly improved. Sustained improvement at 1 yr. Sufficient power.	Moderate

BF = Biofeedback; C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; DRF = digital rectal feedback; F = female; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FU = Followup; HAD = Hospital Anxiety and Depression Scale; ITT = Intention-to-treat analysis; KESS = Knowles-Eccersley-Scott-Symptom Questionnaire for Constipation; mo = month; mg = milligrams; ms = microseconds; PFMT = Pelvic floor muscle training; SF-12 = Short-Form-12 health survey; SF-36 = Medical Outcomes Study Short-Form 36-item Health Survey; T = Treatment group; T_1 = Treatment group 1 T_2 = Treatment group 2 T_3 = Treatment group 3; Vaizey = Vaizey Fecal Incontinence Score; wk = week; y = year

[a]Significant = statistically significant

Table 7. KQ 1. Randomized controlled trial evidence for pelvic floor muscle training with biofeedback (PFMT-BF) versus PFMT alone

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Heymen, 2009[56]	Does PFMT-BF with intrarectal balloon improve FI outcomes over PFMT alone?	N=168 before 4 wk. run-in n=108 (3m, ITT) 77% F; 60 y Mixed T: 6 sessions/3mo FU: 3 mo; only those with adequate relief were followed to 1 y	T: PFMT-BF with intrarectal balloon (45) C:PFMT (63) Both groups: home PFMT 5x/d, educational intervention, and as needed fiber supplement and antidiarrheal drugs	**FISI** (3 mo change), FI days/wk, FIQL (3 mo), adequate relief, STAI-1, STAI-2, BDI	Significant difference in between-group improvements in FISI (no data), continence (44% vs. 21% control) and FI relief (76% vs. 41%) at 3 mo. FIQL similar in both groups; psychological scales unchanged. Underpowered study. Only those with adequate relief at 3 mo. (either group) were evaluated at 1 year.	Moderate
Whitehead, 1985[57]	Does PFMT-BF (with rectal balloon) improve FI over PFMT alone?	N=13 n=13 77% F; 73 y Mixed (geriatric) T: 1+ mo (varied) FU: 6 mo, 12 mo	Crossover: all exercised for 1 mo, then crossover if FI persisted T:PFMT-BF C:PFMT	FI counts/wk	Exercise instruction alone did not decrease FI episodes but there was a significant reduction in FI counts in first 2 wk on biofeedback. Study power not reported	High

BDI = Beck Depression Inventory; BF = Biofeedback; C = Comparator/control; d = day; F = female; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FISI = Fecal Incontinence Severity Index; FU = Followup; ITT = Intention-to-treat analysis; m/mo = month; mg = milligrams; PFMT = Pelvic floor muscle training; STAI = State-trait Anxiety Inventory; T = Treatment group; wk = week; y = year

[a]Significant = statistically significant

Table 8. KQ 1. Randomized controlled trial evidence for PFMT-BF versus PFMT plus education

Author, Year	A	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Ilnyckyj, 2005[58]	Does PFMT-BF with rectal balloon improve FI over PFMT plus education?	N=23 n=18 100% F; 59 y Idiopathic T: 5 wk FU: 5 wk	T:BF (RBT) with PFMT + FI education (7) C: PFMT + FI education (11) *Initial n per group NR*	% without FI	No significant difference in percent of patients without FI (86% treated vs. 45% control); no baseline for FI counts/wk. No sample size calculation. Analyzed completers only.	High

BF = Biofeedback; C = Comparator/control; F = Female; FI = Fecal incontinence; FU = Followup; NR = Not Reported; PFMT = Pelvic floor muscle training; RBT = Rectal Balloon Training; T = Treatment group; wk = week

[a]Significant = statistically significant

Table 9. KQ 1. Randomized controlled trial evidence for PFMT-BF versus PFMT with digital rectal feedback

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Bols, 2012[59]	Does PFMT-BF with rectal balloon improve FI over PFMT (digital rectal feedback)?	N=80 n=80 (ITT) 90% F; 59 years Mixed T: 9 wk FU: 4.5 mo. (varied)	12 sessions/9 wks: T: PFMT-BF plus rectal balloon (40) C: PFMT "alone" (with DRF) (40) PFMT 3x/d (home)	**Vaizey** (0-24); FIQL, GPE	No evidence for add-on benefit of RBT in PFMT; both groups improved. Difference in Vaizey not significant (treated -5.5 vs. controls -4.5); small improvement in other RBT outcomes. Underpowered study (106 needed).	Moderate
Solomon, 2003[60]	Are PFMT-BF (TRUS) & PFMT-BF (AM) superior to PFMT-digital rectal feedback?	N=120 n=120 89% F; 62 years Neuropathic T: 4 mo. FU: 4 mo.	T_1: PFMT-BF (TRUS) (40) T_2: PFMT-BF(AM) (39) C: PFMT (DRF) (41)	**SMFIS**(0-13), Pescatori, FI severity (patient, investigator), 0-10 quality of life	All groups had small improvements. No significant difference in mean improvement from baseline between groups for any outcome. Under-powered study. Analysis of completers likely.	High

AM = Anal Manometry; BF = Biofeedback; C = Comparator/control ; d = day; DRF = digital rectal feedback; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life

scale; FU = Followup; GPE = Global Perceived Effect; ITT = Intention-to-treat analysis; mo = month; Pescatori = Pescatori Fecal Incontinence Score; PFMT = Pelvic floor muscle training; RBT = rectal balloon training; SMFIS = St. Mark's Fecal Incontinence Score; T = Treatment group; T_1 = Treatment group 1 T_2 = Treatment group 2; TRUS = Trans Rectal Ultrasound; Vaizey = Vaizey Fecal Incontinence Score; wk = week

[a]Significant = statistically significant

Table 10. KQ 1. Randomized controlled trial evidence for types of exercise used for PFMT-BF for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits)[a]	Risk of Bias (inverse of quality)
Bartlett, 2011[61]	Compare exercises: PFMT-BF (RBT) mixed exercise vs. PFMT-BF (RBT) sustained contraction	N=72 n=69 (2 m); 53 (2 y) 74% F; 62 y Mixed T: 5 sessions/2 mo FU: 2 mo., 2 y.	5 sessions/8 wk T: PFMT-BF rapid & sustained contraction (35) C: PFMT-BF, sustained contraction (37)	**CCFIS**, FIQL, self-rated improvement	No significant difference between groups in CCFIS improvement at 2 m (-7 vs. -6.5), 2y (-8 vs. -7), or FIQL scales. Improvements maintained at 2 yrs. Sufficient power at 2 mo.	High

BF = Biofeedback; C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FU = Followup; mo = month; PFMT = Pelvic floor muscle training; RBT = Rectal Balloon Training; T = Treatment group; wk = week; y = year
[a] Significant = statistically significant

Table 11. KQ 1. Randomized controlled trial evidence for PFMT-BF with electrostimulation for fecal incontinence: comparison of frequencies

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Schwandner, 2011[62]	Does PFMT-BF with medium freq estim improve FI over PFMT-BF with low freq estim)?	N=80 n=80 (ITT) 81% F; 63 y Mixed T: 6 mo. FU: 3 mo., 6 mo.	T: Estim (medium freq.) with PFMT-BF (39) C (41): Estim (low freq.) with PFMT-BF	**CCFIS**, adapted Vaizey (0-24), FIQL, ICIQ-SF, % complete responders	Significant improvement from baseline in treated vs. controls in CCFIS at 3 mo (-4 vs. 0) and 6 mo (-7 vs. -1); Vaizey, ICIQ-SF and FIQL had similar improvements. 54% complete responders in treated (vs. none). Sufficient power.	Moderate
Schwandner, 2010[63]	Does PFMT-BF with medium freq estim improve FI outcomes over PFMT-BF with low freq estim)?	N=158 n=158 87% F; 63 y Mixed T: 9 mo. FU: 9 mo.	T: PFMT-BF(EMG) plus estim (79) C: PFMT-BF (EMG) (79) 2x/d, 20 min each	**CCFIS** (9 mo), **Vaizey** (9 mo); change in CCFIS, Vaizey at 3 m, 6 m; FIQL; % improved, therapy acceptance	Significantly greater median CCFIS improvement from baseline to 9 mo. in treated vs. controls (mean 2.5 points), 6 mo (2 points) and Vaizey (6 mo). No difference in FIQL between groups. Half of Results tables are per protocol analysis. Adults who deteriorated were analyzed no change group. Attrition 61% at 9 mo.	High

BF = Biofeedback; C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; d = day; EMG = Electromyographic; estim = Electrostimulation; FI = Fecal

incontinence; FIQL = Fecal Incontinence Quality of Life scale; FU = Followup; freq = frequency; ICIQ-SF = International Consultation on Incontinence Questionnaire-Short Form; ITT = Intention-to-treat anal; min = minutes; mo = month; PFMT = Pelvic floor muscle training; T = Treatment group; Vaizey = Vaizey Fecal Incontinence Score; y = year

[a]Significant = statistically significant

Table 12. KQ 1. Randomized controlled trial evidence for PFMT-BF with electrostimulation versus PFMT-BF for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Naimy, 2007[65]	Does PFMT-BF with estim improve FI over PFMT-BF?	N=49 n=40 100% F; 36 y Obstetric trauma T: 8 wk FU: 8 wk	T: PFMT-BF (EMG) plus estim (25) C: PFMT-BF (EMG) (24)	**CCFIS**, FIQL, reduced quality of life (0-10)	No significant difference between groups in CCFIS improvement (-1 both) or other outcomes. Excluded all data from drop-outs (18.4%)	Moderate
Mahoney, 2004[66]	Does PFMT-BF (EMG) with estim improve FI over PFMT-BF (EMG)?	N=60 n=54 100% F; 34 y Obstetric T: 3 mo. FU: 3 mo.	T: PFMT-BF (EMG) plus estim.(20 min) 1x/w (30) C: PFMT-BF (EMG) 10 min 1x/w k (30) Both PFMT (home)	**CCFIS**, FIQL	Both groups improved. Estim with PFMT-BF did not improve outcomes more than PFMT-BF without estim (CCFIS -2 treated, -2.5 control; or FIQL). Completer analysis.	Moderate
Fynes, 1999[64]	Does estim with PFMT-BF improve FI outcomes over PFMT-BF?	N=40 n=39 100% F; 32 y Obstetric trauma T: 3 mo. FU: 3 mo.	T: PFMT-BF (anal EMG) + estim 25 min/wk (20) C: PFMT-BF (vaginal EMG) 30 min/wk (20) Both PFMT (home)	**Modified Pescatori** (0-20?), % asymptomatic	Significant difference in improvement in modified Pescatori between treated and controls (-10 vs. -3). Treatment protocols and therapists differed by group. Power not reported.	Moderate

BF = Biofeedback; C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; EMG = Electromyographic; Estim = Electrostimulation; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FU = Followup; mo = month; Pescatori = Pescatori Fecal Incontinence Score; PFMT = Pelvic floor muscle training; T = Treatment group; wk = week; y = year

[a]Significant = statistically significant

Table 13. KQ 1. Randomized controlled trial evidence for electrostimulation (without PFMT) for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Norton, 2006[67]	Does home-based estim without PFMT improve FI over sham home-based estim?	N=90 n=90 (ITT) 90% F; 55 y Idiopathic T: 2 mo. FU: 2 mo.	T: estim 35Hz 20 min/d x 3w, then 40 min/d x 5w (47) C: same protocol but 1Hz estim (43)	Symptom change outcome rating, FI counts/w, 0-10 of bowel control and satisfaction, effectiveness	No significant difference between groups in any outcome measure. Low treatment compliance: only 25% of treated used estim for 20 h or more (protocol= 34 h). Underpowered study (98 needed)	Moderate
Healy, 2006[68]	Does home-based low-freq. endoanal estim without PFMT improve FI over (hospital-based mixed estim treatment?	N=58 n=38 CCFIS; n=48 other outcomes. 100% F; 54 y Idiopathic T: 3 mo. FU: 3 mo.	T: Estim at home 1h/d (23) C: 30 min. hospital based, 3/wk (25): 1. estim-BF with *muscle contraction* 15 min 1x/wk 2. estim 15 min. 2x/wk	**CCFIS**, SF-36	Within-group analysis: Similar CCFIS improvement in treated (-4.4) and controls (-5.5). SF-36 improved in both. Power not reported. Sparse sample data (in text). Aim was a care site comparison but treatments differed in duration and protocol. Analyzed completers only.	High

C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; d = day; Estim = Electrostimulation; FI = Fecal incontinence; FU = Followup; h = hour; Hz = Hertz; ITT = Intention-to-treat analysis; min = minute; mo = month; SF-36 = Medical Outcomes Study Short-Form 36-item Health Survey; PFMT = Pelvic Floor Muscle Training; T = Treatment group; wk = week; y = year

[a]Significant = statistically significant

Table 14. KQ 1. Randomized controlled trial evidence for interventions to manage fecal incontinence in adults with spinal cord injury

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Christensen, 2006[70]	Compare transanal irrigation to best supportive care	N=87 n=79-87 (ITT) 28% F; 49 y Spinal cord injury T: 10 wks. FU: 10 wks.	T: Transanal irrigation 1x/d then every 2 d or less C: bowel care every 2 d, diet, exercise, stool modifying drugs	**CCCS**, **Vaizey**, modified FIQL, neurogenic bowel dysfunction score (NBDS); satisfaction, bowel function, daily activities	Tested mean differences between groups at termination; baseline comparability not tested. Irrigation significantly better than control on CCCS, Vaizey, NBDS, most other outcomes. 29% of treated discontinued study (4% controls). Sufficient power.	Moderate
Coggrave, 2010[71]	Does stepwise intervention improve bowel management & reduce FI over usual care?	N: 68 n: 68 (ITT) 34% F; 47 y Spinal cord injury T: 6 wk FU: 6 wk	T: Stepwise intervention (7 steps, least to most invasive) (35) C: Usual bowel management (33)	**Duration and level of intervention**, FI frequency, time to stool, minimum level of effective intervention	Stepwise intervention did not improve outcomes or the need for invasive bowel management interventions. FI was significantly more frequent in the treatment group. Underpowered study.	High

C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; d = day; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FU = Followup; ITT = Intention-to-treat analysis; NBDS = neurogenic bowel dysfunction score; T = Treatment group; Vaizey = Vaizey Fecal Incontinence Score; wk = week; y = year

[a]Significant = statistically significant

Table 15. KQ 1. Randomized controlled trial evidence for interventions to manage fecal incontinence in older adults in nursing homes

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Schnelle, 2010[73]	Evaluate a multicomponent intervention on UI and FI in nursing home residents	N: 125 n: 112 83% F; 86 y Mixed T: 12 wk FU: 12 wk	T: toileting assistance, exercise, choice of food, fluid and snacks) 5d/wk (65) C: Usual care (60)	FI counts/d, bowel movements/d, fecal toileting percentage	Frequency of FI did not change with intervention but physical activity, freq. of toileting and food and fluid intake significantly improved. FI difficult to analyze; 45% of residents did not have a bowel movement during baseline or 10 d post-intervention.	High
Schnelle, 2002[72]	Assess benefits of an exercise and incontinence intervention in nursing home residents	N: 190 n: 148 (FI outcome) 83% F; 88 y Not reported T: 32 wk FU: 2 mo 8 mo	T: 4x/d prompted toileting, exercise, fluids (5d/wk) (94) C: No intervention (96)	FI freq (% of checks w/FI), UI freq, fecal and urine toileting ratio, strength and endurance	Significant reduction in FI freq in treated vs. control (4% vs. 1%) at 8 mo (2 mo not reported); significant improvements in all other measures for treated. Power not reported	High

C = Comparator/control; d = day; FI = Fecal incontinence; FU = Followup; freq = frequency; mo = month; T = Treatment group; UI = Urinary Incontinence; wk = week; y = year

[a]Significant = statistically significant

Table 16. KQ 1. Randomized controlled trial evidence for percutaneous tibial nerve versus sacral nerve stimulation

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Thin 2015[74]	Compare PTNS with SNS	N=40 n=31 98% F; 59 y Mixed T: 5 mo (PTNS) FU: 3 mo., 6 mo.	T: PTNS 15 sessions (12 in 3 mo, + 3 over 2 mo.) (16) C: SNS (15)	FI episodes, CCFIS, SF-36, EQ-5D; qualitative interview	Reported within-group changes from baseline; no statistical tests were conducted. Groups differed at baseline on important variables. By 6 mo.,FI episodes (4 to 9 per wk.) and CCFIS (3 to 7 points) improved in both groups but SNS improved more. Minimal change in FIQL and EQ-5D. Excluded post-randomization data on 23% of sample.	Moderate

C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; EQ-5D = EuroQoL Questionnaire-5 Dimensions; FI = Fecal incontinence; FIQL-Fecal Incontinence Quality of Life scale; FU = Followup; mo = month; PTNS = percutaneous tibial nerve stimulation; SF-36 = Medical Outcomes Study Short-Form 36-item Health Survey; SNS = sacral nerve stimulation; T = Treatment group; UI = Urinary Incontinence; y = year

[a]Significant = statistically significant

Table 17. KQ 1. Randomized controlled trial evidence for injectable tissue bulking agents for fecal incontinence

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded if known)	Reported Results (benefits) [a]	Risk of Bias (inverse of quality)
Dehli, 2013[75]	Determine if tissue bulking injections with dextranomer superior to PFMT-BF (plus estim if needed) for FI	N: 126 n: 119 (6 mo) 93% F; 57 y Mixed T: 6 mo control FU: 6 mo.	T: Dextranomer in hyaluronic acid (4 x 1mL injections to anal submucosa); repeat 1x if needed (64) C: PFMT-BF plus estim if needed x 6 sessions/6 mo (62)	**Vaizey** (0-24), FIQL, EQ-5D	No significant difference between groups in Vaizey improvement to 6m (-4.6 points dextranomer vs. -5.4 points PFMT-BF); between group change in FIQL at 6 months not significant; EQ-5D not reported. Sufficient power. Dismissed 44% of sample at 6 months for observational study of successes.	Low
Graf, 2011[76]	Does anal canal injection of dextranomer in hyaluronic acid improve FI over sham injection?	N=206 n=197 (6 mo) 89% F; 61 y Mixed T: Injections (1 d); repeat in 1 mo if CCFIS >10 FU: 3 mo, 6 mo	T: Total of 4-8 ml dextranomer injections in four quadrants of anal submucosa (136) C: Sham injections (nothing injected) (70)	**FI counts/wk (50% or more reduction from baseline**) CCFIS, FIQL, number of FI-free days, decrease in FI episodes	Significant difference in 50% or more reduction in FI episodes/wk in treated (52%) vs. controls (31%) at 6 mo. No differences between groups in CCFIS at 3 mo or 6 mo. FIQL and FI-free days better in treated at 6 mo. Sufficient power. Only followed treated group after 6 mo.	Low
Morris, 2013[78]	Compare bulking agents: Durasphere® (off-label) vs. PTQ™ (non-FDA approved)	N=35 n=34 % F NR; 66 y Not reported T: 1 d FU: 6 wk, 6 mo, 1 y	T_1: Durasphere®: perianal injection (18) T_2: PTQ™ (not-FDA approved) (17)	**CCFIS**, SF-36	Durasphere® only: Improvement in mean CCFIS was 5.3 points at 6 wks., 4.1 at 6 mo., and 1.8 at 1 y. No significant change in SF-36 at any time. Trial underpowered due to early closure of study (from high cost of PTQ™ per authors)	Low
Tjandra, 2009[77]	Compare bulking agents: Durasphere® (off-label) vs. PTQ™ (non-FDA approved)	N=40 n=40 90% F; 59 y Mixed T: 1 day FU: 2 wk, 6 wk, 6 mo, 1 y	T_1: Durasphere®: perianal injection (20) T_2: PTQ™ (not-FDA approved) (20)	**CCFIS**, FIQL, SF-12	Durasphere® only: Improvement in mean CCFIS was 3.2 points at 2 wk, 3.8 at 6 wk, 5.3 at 6 mo, and 4.5 at 1 y. No significant change in SF-12 at any time point. Adequate study power.	Low

BF = Biofeedback; C = Comparator/control; CCFIS = Cleveland Clinic Fecal Incontinence Score; d = day; EQ-5D = EuroQoL Questionnaire-5 Dimensions; Estim = Electrostimulation; FI = Fecal incontinence; FIQL = Fecal Incontinence Quality of Life scale; FU = Followup; FDA = Food and Drug Administration; mo = month; ml = milliliter; PFMT = Pelvic floor muscle training; PTQ™ = injectable bulking agent not FDA approved for use in the U.S.; SF-12 = Short-Form-12 health survey; SF-36 = Medical Outcomes Study Short-Form 36-item Health Survey; T = Treatment group; T_1 = Treatment group 1; T_2 = Treatment group 2; Vaizey = Vaizey Fecal Incontinence Score; wk = week; y = year

[a]Significant = statistically significant

Surgical Treatments

This section includes RCT and OBS studies on surgical treatments for FI including surgically-placed SNS, and combined surgical and nonsurgical treatments. We found only case series studies for SECCA and ACE in adults; those studies are discussed under KQ 2 only.

Key Points

- Evidence is insufficient for all surgical interventions for FI. Few surgical treatments were examined in RCTs or OBS studies; aims and treatments were highly varied and all surgical studies had moderate to high risk of bias.
- The overwhelming majority of surgical studies are case series (low quality evidence).
- Evidence is insufficient for SNS versus supportive care for FI up to 1 year; for turning the stimulator on versus having it off on FI severity and frequency in newly-implanted patients; for stimulation at 75 percent or 50 percent of sensory threshold versus stimulation at sensory threshold; for high-frequency, low prolonged pulse width stimulation to regain efficacy in persons with sustained loss of efficacy after chronic stimulation; and for turning stimulation off versus leaving it on during the night on FI outcomes.
- Surgical outcomes, in general, were reported for longer term followup than for nonsurgical interventions.
- In half of the RCTs where MID was known, outcomes improvements with treatment and sometimes control interventions met or exceeded MID in intermediate-term outcomes (CCFIS, Appendix E), although adults with complications or those lost to follow-up were omitted from half of those analyses.
- Articles commonly lacked important baseline information (such as patient characteristics, FI etiologies and outcomes at enrollment). In particular, SNS studies included minimal nonphysiologic patient information.

Sacral Nerve Stimulation (SNS)

Surgically placed SNS is used when conservative measures have failed to afford the desired level of fecal continence. There are two main limitations of SNS: (1) the stimulator battery has a limited lifetime and needs to be surgically replaced within the stimulator approximately every 5 years and (2) the nervous system adapts to stimulation over time which may result in the loss of efficacy on FI in some adults. Only one RCT[80] assessed the effectiveness of SNS with the stimulator on versus off in newly implanted patients; more recent studies focused on the maintenance of SNS battery life while maintaining continence effects,[81,82] measures to regain SNS efficacy that was dwindling,[83] and the comparison of SNS to best supportive care.[84] All SNS RCTs were crossover studies (Appendix F, Table F4) that almost exclusively enrolled adult females approximately 60 years old with mixed FI etiologies.

The evidence for SNS is insufficient because all five studies had moderate or high risk of bias, and none assessed the same treatment-outcome combination. Evidence is insufficient to compare the effectiveness of SNS versus supportive care on FI outcomes up to 1 year;[84] the effects of turning the stimulator on versus off on FI severity and frequency in newly-implanted patients;[80] stimulation at 75 percent or 50 percent of sensory threshold versus stimulation at sensory threshold;[81] high-frequency, low prolonged pulse width stimulation to regain efficacy in persons

with sustained loss of efficacy after chronic stimulation;[83] and turning stimulation off versus on at night on FI outcomes.[82]

Observational studies provided insufficient evidence for SNS versus sphincteroplasty[85] (Appendix F, Table F5) and open versus percutaneous lead placement[86] (Appendix F, Table F5).

Anal Sphincter Repair (Sphincteroplasty)

Surgical repair of the anal sphincter is performed for adults with FI resulting from anal sphincter tears that have accompanying moderate to severe FI and have suboptimal resolution with conservative treatment. Only two RCTs[87,88] (Appendix F, Table F4) and five observational studies[85,89-92] (Appendix F, Table F5) examined sphincteroplasty.

Observational studies (Appendix F, Table F5) provided insufficient evidence to compare the effectiveness of sphincter repair with stoma (fecal diversion) versus sphincter repair alone;[87] adjuvant biofeedback following anal sphincter repair versus sphincter repair alone;[88] a perineal versus a posterior forchette incision in overlapping anal sphincter repair;[89] sphincteroplasty with pelvic floor repair versus sphincteroplasty;[90] anal sphincter repair versus SNS;[85] sphincteroplasty versus anterior levatorplasty;[91] and direct versus anterior sphincter repair.[92]

Anal Sphincter Replacement

Evidence was insufficient (Appendix F, Table F5) to compare the effectiveness of the artificial bowel sphincter (ABS) versus conservative medical management from one RCT of 14 patients with severe FI,[93] and for the ABS versus a non-FDA approved magnetic anal sphincter[94]).

Other Surgeries and Mixed Treatment Comparisons

Appendix F, Tables F4 and F5 include other surgical studies and mixed treatment comparisons. Evidence was insufficient to compare the effectiveness of total pelvic floor repair versus gluteus maximus transposition without electrical stimulation for postobstetric neuropathic FI;[95] postanal repair versus total pelvic floor repair for neurogenic FI;[96] and total pelvic floor repair versus anterior levatorplasty versus postanal repair for neurogenic FI.[97]

Evidence was insufficient for levatorplasty surgery versus nonsurgical anal plug electrostimulation[98] and for SNS versus a non-FDA approved surgery (magnetic sphincter).[99]

Evidence was insufficient for recommendations after failed sphincteroplasty.[100] Only one high risk of bias observational study compared the outcomes of three surgical treatments used in adults who had at least one prior sphincteroplasty with unsatisfactory outcomes.[100] (Appendix F, Table F5).

KQ 2: What adverse effects are associated with specific treatments for adults with fecal incontinence?

Key Points

- Few nonsurgical RCTs reported adverse effects (AEs). When reported, less invasive nonsurgical treatments had few AEs that were minor.
- Surgical interventions were associated with more frequent and more severe complications than nonsurgical interventions.
- AEs increased as the treatment invasiveness increased and were highest for surgical procedures, especially the artificial bowel sphincter

- Most surgical AEs were identified from surgical case series studies.
- Adverse effects from surgical case series had longer followup than other designs.

Nonsurgical Treatments

Twenty-five of 38 nonsurgical RCTs included adverse effects (AE) reporting, and AEs occurred in 17 of those 25 RCTs (Appendix F, Table F6). Three nonsurgical OBS studies (Appendix F, Table F7) also reported on AEs. Six additional RCTs reported that no AEs occurred (three PFMT, three drug studies). AEs were generally mild and varied by the type of intervention; the frequency of AEs was variably reported (overall, by group or only identified in text). Gastrointestinal symptoms occurred with fiber supplements in 5 percent[39] to 20 percent[36] of patients. Oral medications used for FI were most commonly associated with nausea and abdominal pain. Nonserious AEs of abdominal pain, headache, and nausea were reported for 55 percent of adults treated with 8mg of loperamide per day in one RCT;[43] no adverse effects at 12mg/day in another RCT;[44] and abdominal pain, headache, and nausea and vomiting in 69 percent of patients on 12mg in another RCT.[45] No adverse effects occurred in PFMT-BF studies that reported them. PFMT-BF with electrostimulation at low frequency caused pain in 50 percent of patients in the control group but no pain in the high-frequency treatment group.[62] Electrostimulation without PFMT caused discomfort in 9 percent of patients.[67] No AEs occurred with rectal irrigation in adults with passive FI.[69] However, bursts of the rectal balloon during rectal irrigation occurred in one in every three adults with spinal cord injuries;[70] abdominal distention and hospitalization for severe constipation occurred infrequently in these adults.[70] Repeated expulsion of the rectal catheter during irrigation was common in adults with SCI.[70] No serious AEs occurred with PTNS, although 6 percent experienced transient pain or paresthesias.[74]

In general, placebo or comparison group AE rates varied widely but were less frequent (none to half of treatment rates) and less severe than treatment group AEs (Appendices F6 and F7).

Tissue bulking injections had the highest proportion and variety of complications of the nonsurgical treatments (Appendix F, Table F6). Reported in aggregate, 25 percent of patients treated with dextranomer in hyaluronic acid experienced leakage of the injected agent, infection, or prolonged defecation over 6 months.[75] A dextranomer versus sham study[76] reported treatment complications of proctalgia (14%), rectal hemorrhage (7%), diarrhea (5%), constipation (2%), injection site bleeding (5%), rectal discharge (4%), anal pruritus (2%), proctitis (3%), painful defecation (2%), fever (8%), other (16%) versus sham (injection site bleeding [17%]), and other minor effects in 1-7 percent of patients. Durasphere® tissue bulking injections were associated with no AEs in one study[78] but another study reported local bruising (20%), erosion through the rectal mucosa (10%), and rectal pain or hypersensitivity reaction in 5 percent of patients.[77]

Surgical Treatments

Adverse effects from surgical treatments were reported in eight OBS (Appendix F, Table F7), seven RCTs (Appendix F, Table F8), and 53 case series studies (Appendix F, Table F9). Surgical complications were common and ranged from minor (swelling, hematoma) to major (infection, bowel obstruction, perforation, fistula); major complications often required reoperation; some required a permanent colostomy.

The frequency of surgical complications ranged from 0-32 percent in SECCA;[101-106] 21-74 percent in ACE;[107-110] 5-27 percent with sphincter repair;[87,89-92,100,111-119] 2-93 percent with

SNS;[74,80,84,86,99,100,120-138] 8-64 percent with other surgeries;[95,97,98,139] and 22-100 percent with sphincter replacement.[93,94,100,140-153]

The severity of adverse effects varied by the type of surgery (Appendix F, Tables F7-F9). Adverse effects were generally less severe for SECCA (pain, bleeding, swelling, mucosal ulceration) and SNS (infection, pain, electrode/lead issues, device malfunction). However, SNS required reoperation in 3 percent to 41 percent of patients for device-related complications, and 3 percent to 24 percent of SNS patients had the device explanted. ACE, sphincter repair and sphincter replacement had the most severe complications (wound infection, stenosis, bowel obstruction, sepsis, leak, and fistula). The most frequent and severe complications occurred with sphincter replacement with an artificial bowel sphincter: infections were very common and 14 percent to 81 percent of recipients underwent surgical explant of the device and either replaced (most often) or treated with colostomy (less often).

Discussion

Key Findings and Strength of Evidence

We found low-quality evidence to inform clinical decisionmaking for nonsurgical treatments for FI in adults in the United States. The evidence situation is worse for virtually all surgical treatments compared with nonsurgical therapies. The evidence of effectiveness is insufficient for all surgical treatments. More invasive surgical procedures are often associated with considerable complications. We were unable to conduct a meta-analysis because few studies examined the same treatment-outcome combination within similar timeframes and outcome measures varied widely. Table 18 summarizes the major findings of this review; supporting details of the strength of evidence assessments are provided in Appendix F, Table F10; risk of bias ratings for individual studies that informed the strength of evidence assessments are in Appendix F, Tables F11 and F12, respectively.

Low-strength evidence suggests that dietary fiber supplementation with psyllium decreases FI episode frequency by 2.5 occurrences per week after 1 month of use; that clonidine has no effect at 1 month; and that PFMT-BF with electrostimulation is no more effective than PFMT-BF on FI severity and changes in the FIQL instrument scores over 2 to 3 months.

Low-strength evidence at 6 months post-treatment suggests that dextranomer anal tissue-bulking injections are more effective than sham injections on FIQL, the number of FI-free days, and on the percent of patients with FI episode reduction of 50 percent or more from pre-injection levels, but no more effective than PFMT-BF with or without electrostimulation on FI severity and quality of life, and no more effective than sham injection on FI severity (CCFIS) or in reducing the number of FI episodes from baseline. The only anal sphincter tissue bulking agent examined in a randomized trial beyond 6 months was Durasphere® (off-label), which showed improvements in FI severity up to 6 months. However, gains with Durasphere® diminished slightly between 6 months and 1 year post-injections in two RCTs.[77,78]

Although PFMT has been successful in addressing urinary incontinence,[154] the included PFMT literature focused mainly on refinements in treatment delivery to improve or prolong purported benefits of PFMT for FI rather than on establishing its benefits. Various iterations of PFMT produce similar improvements that appear to meet MID (Appendix E) when those measures were used (CCFIS,[155] FISI,[156] Vaizey,[155,157] and FIQL subscales[155]). We found insufficient evidence that PFMT-BF offers any advantage over standard care (such as dietary fiber supplementation, stool-modifying drugs, and education) for FI. Assessing PFMT-BF training for FI was made difficult by the lack of standard protocols; no included studies used the same treatment protocol for timing, intensity, type, and duration of exercise. Some articles provided no information on exercise repetitions and duration, despite including intricate details regarding biofeedback sensors, probe placement, and patient positioning.

The evidence for FI treatment benefits was insufficient for all other nonsurgical and surgical interventions. Thus this literature provides little guidance for primary care providers and patients in their selection and sequencing of treatments for FI. Limitations in study conduct were common and generally avoidable. In particular, study reporting did not match the longstanding reporting recommendations of CONSORT.[158-160]

Table 18. Strength of evidence summary for nonsurgical treatments for fecal incontinence[a]

Comparison	Type of FI Measure	Outcome, Study Information	Findings	Strength of Evidence (rationale by domain)
Dietary fiber supplementation with psyllium vs. placebo	Severity	FI episodes per week, 1 RCT[36] N=206	Psyllium significantly decreased FI by 2.5 episodes per week vs. placebo (0.7 fewer episodes/week) at 1 month	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])
Clonidine (oral) 0.2 mg/day vs. placebo	Severity	Mean weekly FICA 1 RCT[47] N=44	No significant difference between groups in FICA improvement at 1 month (1.6 points clonidine vs. 1.5 placebo)	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])
PFMT-BF plus electrostimulation vs. PFMT-BF	Severity	CCFIS, 2 RCTs[65,66] N=109	No significant difference between groups in mean CCFIS improvement at 3 months: -1 point in both groups,[61] -2 points treated, -2.5 points control[62]	**Low** (medium study limitations, direct, imprecise, consistent)
	Quality of life	FIQL, 2 RCTs[65,66] N=109	No significant difference in FIQL between groups at 2 to 3 months; neither group improved (0 to 0.3 point change from baseline per subscale)	**Low** (medium study limitation, direct, precise, consistent)
Dextranomer tissue bulking injections vs. PFMT-BF +/- electrostimulation	Severity	Vaizey score 1 RCT[75] N=126	No significant difference between groups in Vaizey improvement at 6 months (-4.6 points dextranomer vs. -5.4 points PFMT-BF)	**Low** (medium study limitations, direct, imprecise, consistency unknown [single study], reporting bias detected)
	FI Quality of life	FIQL 1 RCT[75] N=126	No significant difference between groups in FIQL at 6 months (per text and figures; values not reported)	**Low** (medium study limitations, direct, imprecise, consistency unknown [single study], reporting bias detected)
Dextranomer tissue bulking injections vs. sham injections	Severity	CCFIS 1 RCT[76] N=206	No significant difference between treated vs. sham in CCFIS improvement at 3 months (-2.6 points dextranomer vs. -2 sham) and 6 months (-2.5 points dextranomer vs. -1.7 sham)	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])
	Severity	FI severity 1 RCT[76] N=206	Significant difference in percent of patients with ≥50% reduction in FI episodes at 6 months: 52% of dextranomer group vs. 31% sham. Median decrease in number of FI episodes over 2 weeks was not significantly different between groups at 3 months or 6 months (6.0, IQR 0-12.5) vs. 3.0 sham, IQR 0-8.9: p=0.09). Mean increase in number of FI-free days was greater in treated (3.1 days, SD 4.1) vs. sham (1.7 days, SD 3.5) group	**Low** (low study limitations, direct, imprecise; 3 measures gave inconsistent results: 2 better, 1 no different)
	FI Quality of life	FIQL 1 RCT[76] N=206	Percent change (improvement) from baseline in FIQL coping-behavior subscale favored dextranomer at 6 months: 27% (CI 21%, 34%) vs. sham 11% (CI 3%, 18%). Change scores in 3 other subscales did not differ (per text and figures, values not reported)	**Low** (low study limitations, direct, imprecise, consistency unknown [single study])

Comparison	Type of FI Measure	Outcome, Study Information	Findings	Strength of Evidence (rationale by domain)
Durasphere® (off-label) tissue bulking injections vs. non-FDA approved PTQ™ injections	Severity	CCFIS 2 RCTs[77,78] N=75	Durasphere® (FDA-approved) results:[b] Mean CCFIS improvements were: 5.3 points at 6 weeks, 4.1 at 6 months, 1.8 at 1 year, [77] 3.8 points at 6 weeks, 5.3 at 6 months, 4.5 at 1 year[76]	**Moderate** (low study limitations, direct, imprecise, consistent)

C=Comparator/control; CCFIS=Cleveland Clinic Fecal Incontinence Score; EQ-5D=EuroQoL Questionnaire-5 Dimensions; Estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FDA=Food and Drug Administration; IQR=interquartile range; PFMT=Pelvic floor muscle training; PTQ™=injectable bulking agent not FDA approved for use in the U.S.; RCT=randomized controlled trial; SD=standard deviation; Vaizey=Vaizey Fecal Incontinence Score

[a]Table shows strength of evidence for treatment-outcomes combinations with at least 2 moderate risk of bias RCTs or 1 RCT with low risk of bias and sufficient power to assign low strength of evidence. Other comparisons with insufficient evidence are not shown.
[b]Non-FDA approved comparator PTQ™ results are not discussed.

FI treatment generally follows a longitudinal sequence, which complicates efforts to compare surgical and nonsurgical interventions. Patients earlier in their FI course typically receive nonsurgical treatment, and those who do not respond to nonsurgical treatments may then be offered surgery. Additionally, nonsurgical treatment is often used as an adjunct to surgery, whereby patients continue dietary modification, stool-modifying drugs, and sometimes PFMT after surgery.

Understanding the effectiveness of the range of FI treatments requires carefully defining the nature of the patients at risk in terms of underlying problems, clinical characteristics, and prior treatment history. Many included studies failed to provide this information. Nonsurgical studies focused on short-term or intermediate-term outcomes in the management of FI, leaving many unanswered questions about the durability and feasibility of interventions over time.

Aside from adults in nursing homes and those with spinal cord injuries, we were unable to report subgroup-specific outcomes due to the heterogeneity of FI etiologies in enrolled adults in the studies that reported etiology. The majority of enrolled adults were females and their FI etiologies were most often mixed or not reported.

Adverse effects from nonsurgical interventions are uncommon and tend to be minor. In contrast, AEs from surgical interventions are common and often substantial. For some procedures, complications may occur years after the surgery. The severity of complications increases with invasiveness of the treatment. Most of the surgical adverse effects were identified from case series. However, we felt confident using case series for surgical complications because these problems were extremely unlikely to arise among controls who did not receive surgery. Complications from ACE, sphincter repair, and sphincter replacement were most severe. SNS complications were less severe, but all of these treatments may require further surgery. Removal of SNS was required in up to one in four recipients. The highest complications of any surgical procedure for FI were reported for sphincter replacement (ABS). The ABS required surgical removal (explant) in 20-81percent of patients; infections were common and some patients ultimately required permanent colostomy. Significant complications are important to consider when providers are counseling patients with severe FI.

Findings in Relationship to What Is Already Known

We examined the comparative effectiveness of treatments for FI across the range of treatments available to adults in the United States. In contrast, prior systematic reviews typically examined evidence within single modes of FI treatment, such as such as surgery or drugs.[6-9,13,14,16,17,161-163] Similar to our findings, single-treatment-mode systematic reviews found weak evidence for most FI treatments, and similar literature limitations (small number of studies, small patient samples, and substantial methodological limitations), leaving little definitive evidence to support specific treatments for FI. This review adds unique comparative information to assist providers and patients in clinical decisions among several treatment options.

We found FI treatment guidelines from two professional societies: the American College of Gastroenterology (ACG),[164] and a recent guideline available from the American Society of Colon and Rectal Surgeons (ASCRS).[165]

Appendix F, Table F13 provides a table that contrasts the recommendations of these guideline groups and the findings in this review. Injectable tissue bulking injections received weak support by ASCRS and ACG, which is consistent with the findings of this review. No other professional society recommendations could be supported by the results of this review. Both societies supported combined nonsurgical treatments (diet, antidiarrheal drugs, education). Colorectal surgeons more strongly favored surgical approaches than did the gastroenterologists; both groups supported SNS, which had insufficient evidence in this review. Many treatments examined in this review were not mentioned in either guideline (dietary fiber [alone], other drugs, PFMT versus other comparators, PFMT-BF with electrostimulation, electrostimulation without PFMT, rectal irrigation [alone], and interventions for older adults in nursing homes).

Applicability and Limitations of the Evidence Base

Several important characteristics limit the generalizability and applicability of the studies reviewed. Overall, the evidence base would benefit from better compliance with CONSORT[158] and greater efforts to avoid compromising study integrity by analyzing only completers or those with perfect compliance, or by aggregating data from those whose condition deteriorated with those who remained stable.

The large number of outcome measures in RCTs alone impeded comparability across studies and the ability to conduct meta-analysis. The field would benefit from using a more consistent set of outcome measures to facilitate comparability. In cases where a new assessment tool is used, simultaneously including a validated, commonly used measure would facilitate interpretation. The wide heterogeneity in current measures leaves the field with many unique, often underpowered studies for a particular intervention and/or subgroup, which provides insufficient evidence to inform clinical decisions.

Common outcome measures need standardized labels across all disciplines that treat adults with FI. Measures that underwent several iterations, including changes in content and scale, were variably identified and often mislabeled, even in recent literature. For example, the Vaizey FI score (0-24[26]) was sometimes labeled as "St. Mark's" (0-13[28]), yet baseline or outcomes values, or the reference (when cited) for the measure, made it obvious that the Vaizey score had been used.[75,81-83] The Cleveland Clinic Fecal Incontinence Score (CCFIS)[24] was also variably labeled as CCFIS, Wexner or Jorge/Wexner in the articles we reviewed.

More uniformity in both how FI episodes are defined and graded for severity would improve comparability across studies. Definitions of FI episodes were particularly difficult to compare

across studies (soiling versus solid stool versus solid plus liquid stool versus liquid only). FI severity was defined in numerous ways (episode frequency, CCFIS or other scale at screening, etc.), and was often used as a sample selection criteria in clinical studies. Mild to severe grading is problematic because FI severity grading is not standardized. Moreover, clinicians and patients sometimes disagree on FI severity ratings for a given patient situation.[25] Definitions of urgency also varied in the few studies that measured it. Input from adults with FI may suggest ways to identify and quantify aspects of FI that can capture what matters most to patients in outcome measures. Issues with urgency may be just as problematic to patients as actual FI episodes, since the uncertainty and fear of accidental bowel leakage surrounding urgency require, at minimum, the same prompt behavior: finding a toilet.

Inconsistencies in the labeling of PFMT were particularly confusing. Clinical studies and one guideline[165] labeled this entire group of treatments as *biofeedback*, which is a vehicle by which PFMT is enhanced, not the treatment itself. Given that biofeedback is used to enhance many types of treatments, efforts to standardize labels used for the various iterations of PFMT in the literature (PFMT, PFMT-BF, PFMT-BF with electrostimulation) would be helpful for readers.

The value of intermediate physiologic measures is unclear given the lack of a well-established link between physiologic measures and patient-centered outcomes. Manometric and other physiologic measures are overabundant, but far more information is needed about typical patient demographics, clinical features, and status at baseline. The latter data would better contextualize study results and help to inform which treatments work best in which patients.

Although FI is a chronic problem, most evidence is only short or intermediate term; longer term information on both benefits and adverse effects would better inform clinical decisions for chronic FI management.

Although we had hoped to use etiology as a basis for assessing FI treatments, we could not because the material on etiology was often unclear, incomplete, or absent. Often no dominant etiology was described. Multiple etiologies may contribute to FI, and etiologies were variably reported or implied in the literature. One-third of RCTs provided no etiologic information, while other authors provided great detail of nonmutually exclusive contributing factors. No study provided information about the frequency of multiple FI etiologies per enrolled adult in baseline patient information tables, such as summary counts per patient or common etiologic combinations. Baseline testing was commonly conducted to ascertain the presence and degree of anal sphincter tearing, but further etiologic identification was less commonly reported. In addition to FI severity at baseline, etiologic multiplicity information could advance understanding of which etiologic factors respond best to given treatments or treatment combinations. Additionally, the term *neurogenic FI* would benefit from standardization. Aside from its use in the presence of significant nervous system pathology, *neurogenic FI* appears to be a catch-all term for any FI etiologies in the absence of identified structural pathology. Nonetheless, such distinctions were unclear. Careful descriptions of patients in clinical studies, including baseline characteristics, comorbid conditions (including urinary incontinence) and FI etiologies, would improve understanding of the applicability of results from individual studies and facilitate future literature syntheses.

Well-designed and conducted prospective cohort studies are underused in FI and may better identify baseline patient, FI severity, and etiologic factors more than highly selected RCT samples and also help to determine how such factors affect outcomes from various approaches over time. Most of the observational studies with comparators that we reviewed had extensive study limitations that rendered invalid any treatment conclusions about differences between

groups. Common limitations within individual studies were noncomparable intervention and control groups that differed on important prognostic factors at baseline (such as prior surgery or age), and inconsistent timing of outcomes assessments (ranged from months to years and often varied by study group), with no or inadequate efforts to adjust for these differences.

We did not find RCT or OBS evidence for all available FI treatments. The studies included in this review may not reflect the frequency of which specific treatments are used in clinical practice. For example, the easiest treatments to study (drugs) are not necessarily those that are used most often. According to our TEP, topical medications, narcotics, and one or two surgical procedures are no longer commonly used but are still FDA-approved for use in the United States.

Finally, a segment of the FI literature we reviewed lacked baseline patient information that described enrolled adults in person-centered terms. This was especially true for (but not limited to) most SNS studies. Aside from limited treatment metrics of interest to investigators, baseline information surrounding patients and their FI experience (etiology, duration, and severity) was missing; enrolled adults were identified largely by their physiologic (sphincter) metrics. The lack of baseline patient information in a segment of the FI literature was unexpected, given the longstanding recommendations of CONSORT.[158-160]

Limitations of the Review Process

Meta-analysis was not possible because numerous outcomes were used.

We were unable to report potential differences in treatment effectiveness within FI etiologic subgroups because FI is often multifactorial. Most studies included adults with mixed FI etiologies. In many instances, little information on etiology was provided at baseline.

Outcomes assessments were often timed at unusual intervals, necessitating our aggregation of evidence into short-term (less than 3 months), intermediate-term (3 to 6 months), or long-term (more than 6 months) effects.

While this review was limited to English-language publications, the possibility of missing clinical trials for FDA-approved treatments in the United States is remote.[166,167]

We did not examine the FDA Adverse Event Reporting System for drug harms.

We did not contact authors for missing data or clarification of ambiguous or indeterminable table and text information.

Research Gaps

The overall strength of evidence for treatments for FI in adults was low or insufficient, suggesting that future studies with higher quality could change the conclusions of this review. Many research gaps are identified above in Applicability and Limitations of the Evidence Base. We first provide overarching comments that could advance the field of FI research given the information we noted during this review, followed by specific research gaps that we identified.

Two levels of research improvements would likely advance the field: 1) Clinical research needs to be properly conducted and accurately reported in accordance with CONSORT criteria. For example, it is essential to report data from all randomized adults to minimize attrition bias. Eliminating data from adults who did not respond favorably to treatment, were lost to followup, or had suboptimal treatment compliance is not acceptable. 2) Moving the field to a higher level of research quality may require establishing academic research/clinical centers that will allow for a more structured team approach to research question development, study design selection, enhanced patient input into outcome measure development, the assessment of simultaneous treatments, improved FI etiologic classification, better co-intervention tracking, and the

minimization of losses to followup. Funding mechanisms such as the P01 or P50 program grants from the National Institutes of Health could support such clinical research activities. Such centers could be regional centers that do high volume work in FI or they could be research centers that coordinate multicenter studies, providing strong research designs and assuring fidelity to treatment.

Validated outcome measures that capture the FI impact features most meaningful to patients are critical, in addition to the standardized labeling of such measures across studies (see Applicability and Limitations of the Evidence Base); only some of the current outcome measures solicited patient input during instrument construction.

Some specific aspects of FI treatment deserve more attention, including the durability of treatment effects over time. Short-term, easy-to-use treatments, such as drugs and fiber supplements, may be important for planning around important social events, but it is unclear whether their beneficial effects are sustained longer term. Little information was available on rectal irrigation for adults with FI unrelated to spinal cord injury, yet rectal irrigation may prove to be a viable management tool, at least in the short term.

Few if any treatments can entirely cure FI; therefore, information on treatment combinations would benefit the evidence base. This is especially true since many interventions, once initiated, are continued long term. Dietary fiber, intermittent stool modifying drugs, and PFMT-BF may all be used pre- and post-surgery, but patients who would best benefit from combined therapies are not well identified.

Further research is needed to establish what elements of PFMT-BF work for FI, and for how long. Intervention specifics including the optimal type of exercise, duration, number of repetitions, frequency, and specific patients and FI etiologies for which PFMT-BF is effective or ineffective are lacking. Long-term exercise compliance with PFMT-BF for FI is unknown.

Since the benefit of surgical interventions, including sacral nerve stimulation, may diminish over time, more work is needed to determine which additional interventions should be undertaken and when they should be initiated to enhance or prolong the durability of surgical benefits.

We do not know whether the degree of external sphincter defect predicts the outcome of sacral nerve stimulation or nonsurgical treatment. Older studies excluded patients with extensive tears. However, lower-quality observational studies report that even patients with extensive tears improved with SNS up to 1 year.[168,169]

Information is limited about the results of treatment options chosen after failed surgical treatments.[100]

Better comparison of the benefit-to-harm ratio of FI treatments is needed, especially for invasive and surgical interventions. Substantial and life-altering adverse events occur post-surgery for FI, and these were under identified in RCTs alone.

The long-term effects of injected anal bulking agents are unclear, including their effects on adjacent normal tissues and the location of the injected substance itself.

More work is needed to identify ways to improve outcomes for adults with FI and spinal cord injuries and for older adults in nursing homes. Interventions for nursing home residents with FI focused on the prevention of fecal impaction, though staff-implemented interventions that gave greater attention to fluid, diet, and toileting measures, none of which improved FI outcomes.

Studies of FDA and non-FDA approved interventions in ClinicalTrials.gov that may eventually mitigate some of these research gaps include, but are not limited to, interventions for older adults (multicomponent [behavioral, education, medication] FI intervention delivered by

home health nurses to frail elderly patients, effect of a nursing home staff education program on FI in residents, surgically-placed TOPAS mesh sling [pelvic floor] for women with FI, pelvic floor muscle training, botulinum toxin A injections on FI and urgency, long-term safety and efficacy of Solesta [dextranomer injection], percutaneous tibial nerve stimulation for FI, plus several studies of injections of biologics including stem cells). Also, a case series was recently published for a new nonsurgical vaginal bowel control device.[12]

Implications for Clinical and Policy Decisionmaking

The current FI literature base lacks high-quality research evidence to inform clinical practice or policy. Given the clinical complexity of many adults with FI, potential new centers that could generate better research evidence and manage patients in multidisciplinary settings may be the next best step to advance both research and patient care (see Research Gaps above). In the absence of such centers, many adults with FI coordinate their own care between multiple disciplines and multiple sites, making managing FI and FI care a full-time job, especially for more severely afflicted individuals.

Conclusions

Only a few nonsurgical treatments for FI in adults had sufficient-quality evidence to inform patient care; the surgical evidence is of insufficient quality for clinical decisionmaking. The use of numerous outcome measures impedes the field. Substantial methodological and reporting issues can be rectified by following current study and reporting standards; small improvements could provide higher quality evidence. The overall strength of evidence for treatments for FI in adults was low or insufficient, suggesting that future studies with higher quality could change the conclusions of this review.

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169. Chan MK, Tjandra JJ. Sacral nerve stimulation for fecal incontinence: external anal sphincter defect vs. intact anal sphincter. Dis Colon Rectum 2008 Jul;51(7):1015-24; discussion 24-5. PMID: 18484136.

Abbreviations

ABL	Accidental bowel leakage
ABS	Artificial bowel sphincter
ACE	Antegrade colonic irrigation
AE	Adverse effect
AHRQ	Agency for Healthcare Research and Quality
AMED	Allied and Complementary Medicine
CENTRAL	Cochrane Central Register of Controlled Trials
CER	Comparative effectiveness review
CCFIS	Cleveland Clinic Fecal Incontinence Score
FDA	Food and Drug Administration
FI	Fecal incontinence
FICA	Fecal Incontinence and Continence Assessment
FIQL	Fecal Incontinence Quality of Life Instrument
FISI	Fecal Incontinence Severity Index
GI	Gastrointestinal
KQ	Key Question
MID	Minimum important difference
OBS	Observational Studies
PEDro	Physiotherapy Evidence Database
PFMT	Pelvic floor muscle training
PFMT-BF	Pelvic floor muscle training with biofeedback
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, Setting
PTNS	Posterior tibial nerve stimulation
RCT	Randomized controlled trial
SCI	Spinal cord injuries
SECCA	Radiofrequency anal sphincter remodeling
SIP	Scientific Information Packet
SNS	Sacral nerve stimulation
SOE	Strength of evidence
TEP	Technical expert panel

Appendix A. Analytic Framework for Treatments for Fecal Incontinence

Figure A1. Analytic framework for treatments for fecal incontinence

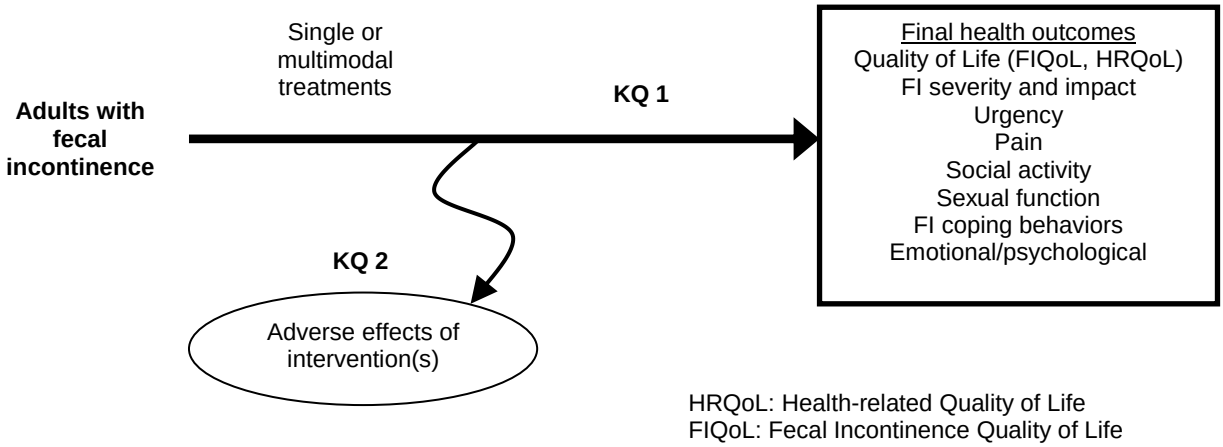

Figure A1 depicts the two key questions within the context of the PICOTS described in Table 1 of the report. The figure above illustrates how the use of single or multimodal treatments for fecal incontinence may improve outcomes for adults with fecal incontinence. This systematic literature review included adults who underwent treatment for fecal incontinence. The Key Question 1 final health outcome categories include quality of life (health-related or specific to fecal incontinence), FI severity and impact (continence measures), urgency, pain, social activity, sexual function, the use of coping behaviors to manage fecal incontinence, and emotional or psychological measures. Adverse effects of drugs or interventions may also occur at any point after the treatment is initiated; these were examined in Key Question 2.

Appendix B. Search Strings

Database: Ovid MEDLINE(R)

Search Strategy: RCTs

---

1 meta analysis as topic/
2 meta-analy$.tw.
3 metaanaly$.tw.
4 meta-analysis/
5 (systematic adj (review$1 or overview$1)).tw.
6 exp Review Literature as Topic/
7 or/1-6
8 cochrane.ab.
9 embase.ab.
10 (psychlit or psyclit).ab.
11 (psychinfor or psycinfo).ab.
12 or/8-11
13 reference list$.ab.
14 bibliograph$.ab.
15 hand search.ab.
16 relevant journals.ab.
17 manual search$.ab.
18 or/13-17
19 selection criteria.ab.
20 data extraction.ab.
21 19 or 20
22 review/
23 21 and 22
24 comment/
25 letter/
26 editorial/
27 animal/
28 human/
29 27 not (28 and 27)
30 or/24-26,29
31 7 or 12 or 18 or 23
32 31 not 30
33 randomized controlled trials as topic/
34 randomized controlled trial/
35 random allocation/
36 double blind method/
37 single blind method/
38 clinical trial/
39 clinical trial, phase i.pt.
40 clinical trial, phase ii.pt.
41 clinical trial, phase iii.pt.

42 clinical trial, phase iv.pt.
43 controlled clinical trial.pt.
44 randomized controlled trial.pt.
45 multicenter study.pt.
46 clinical trial.pt.
47 exp Clinical trials as topic/
48 or/33-47
49 (clinical adj trial$).tw.
50 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.
51 placebos/
52 placebo$.tw.
53 randomly allocated.tw.
54 (allocated adj2 random$).tw.
55 49 or 50 or 51 or 52 or 53 or 54
56 48 or 55
57 case report.tw.
58 case report.tw.
59 letter/
60 historical article/
61 57 or 58 or 59 or 60
62 56 not 61
63 exp cohort studies/
64 cohort$.tw.
65 controlled clinical trial.pt.
66 epidemiologic methods/
67 limit 66 to yr=1971-1983
68 63 or 64 or 65 or 67
69 exp Fecal Incontinence/
70 f?ecal incontin*.ti,ab.
71 69 or 70
72 62 and 71
73 limit 72 to "all child (0 to 18 years)"
74 limit 73 to "all adult (19 plus years)"
75 72 not 73
76 75 or 74

Database: Ovid MEDLINE(R)
Search Strategy: Observational & Systematic Reviews

---

1 meta analysis as topic/
2 meta-analy$.tw. 3 metaanaly$.tw.
4 meta-analysis/
5 (systematic adj (review$1 or overview$1)).tw.
6 exp Review Literature as Topic/
7 or/1-6
8 cochrane.ab.
9 embase.ab.
10 (psychlit or psyclit).ab.
11 (psychinfor or psycinfo).ab.
12 or/8-11
13 reference list$.ab.
14 bibliograph$.ab.
15 hand search.ab.
16 relevant journals.ab.
17 manual search$.ab.
18 or/13-17
19 selection criteria.ab.
20 data extraction.ab.
21 19 or 20
22 review/
23 21 and 22
24 comment/
25 letter/
26 editorial/
27 animal/
28 human/
29 27 not (28 and 27)
30 or/24-26,29
31 7 or 12 or 18 or 23
32 31 not 30
33 Epidemiologic studies/
34 exp cohort studies/
35 exp case control studies/
36 Case control.tw.
37 (cohort adj (study or studies)).tw.
38 contro*.tw.
39 Cohort analy$.tw.
40 (Follow up adj (study or studies)).tw.
41 (observational adj (study or studies)).tw.
42 Longitudinal.tw.
43 or/33-42
44 exp *Fecal Incontinence/

45 f?ecal incontin*.ti.
46 44 or 45
47 32 or 43
48 46 and 47
49 limit 48 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)")
50 limit 49 to ("all adult (19 plus years)" or "young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)")
51 48 not 49
52 50 or 51
53 limit 52 to (autobiography or bibliography or biography or clinical conference or comment or congresses or consensus development conference or dataset or dictionary or directory or editorial or in vitro or interactive tutorial or interview or lectures or legal cases or letter or news or newspaper article or patient education handout or periodical index or portraits or validation studies or video-audio media or webcasts)
54 52 not 53
55 32 and 54
56 limit 55 to yr="2007 -Current"
57 43 and 54
58 limit 57 to yr="2014 -Current"
59 (anal and incontin*).ti.
60 43 and 59
61 43 and 46 and 60
62 61 not 60
63 58
64 from 63 keep 1-33

Database: Embase
Search Strategy: RCTs

---

1 Clinical trial/
2 Randomized controlled trial/
3 Randomization/
4 Single blind procedure/
5 Double blind procedure/
6 Crossover procedure/
7 Placebo/
8 Randomi?ed controlled trial$.tw.
9 Rct.tw.
10 Random allocation.tw.
11 Randomly allocated.tw.
12 Allocated randomly.tw.
13 (allocated adj2 random).tw.
14 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15 Case study/
16 Case report.tw.
17 Abstract report/ or letter/
18 15 or 16 or 17
19 14 not 18
20 exp feces incontinence/
21 f?ec* incontinence.ti,ab.
22 20 or 21
23 limit 22 to "therapy (maximizes specificity)"
24 19 and 22
25 23 or 24
26 limit 25 to (embryo <first trimester> or infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)
27 limit 26 to (adult <18 to 64 years> or aged <65+ years>)
28 25 not 26
29 27 or 28
30 limit 29 to (book or book series or conference abstract or conference paper or conference proceeding or "conference review" or editorial or letter or note or report or "review" or short survey or trade journal) (747)
31 29 not 30 (893)

Database: Embase
Search Strategy: Observational & Systematic Reviews

---

1 exp cohort analysis/ (174551)
2 exp longitudinal study/ (63150)
3 exp prospective study/ (242937)
4 exp follow up/ (756554)
5 cohort$.tw. (402905)
6 1 or 2 or 3 or 4 or 5 (1292797)
7 exp case-control study/ (84810)
8 (case$ and control$).tw. (358942)
9 7 or 8 (386956)
10 (case$ and series).tw. (126465)
11 exp review/ (1524716)
12 (literature adj3 review$).ti,ab. (165004)
13 exp meta analysis/ (79651)
14 exp "Systematic Review"/ (80673)
15 11 or 12 or 13 or 14 (1686250)
16 (medline or embase or pubmed or cinahl or amed or psychlit or psychinfo or scisearch or cochrane).ti,ab. (110973)
17 retracted article/ (6623)
18 16 or 17 (117548)
19 15 and 18 (87911)
20 (systematic$ adj2 (review$ or overview)).ti,ab. (77973)
21 (meta?anal$ or meta anal$ or metaanal$ or metanal$).ti,ab. (84784)
22 19 or 20 or 21 (176214)
23 exp *feces incontinence/ (4452)
24 f?ecal incontin*.ti. (2291)
25 23 or 24 (4492)
26 limit 25 to (meta analysis or "systematic review") (67)
27 22 and 25 (129)
28 26 or 27 (143)
29 6 or 9 or 10 or 28 (1684571)
30 25 and 29 (1257)
31 limit 30 to yr="1980 -Current" (1257)
32 limit 31 to (embryo <first trimester> or infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years>) (153)
33 limit 32 to (adult <18 to 64 years> or aged <65+ years>) (47)
34 31 not 32 (1104)
35 33 or 34 (1151)
36 limit 35 to (book or book series or conference abstract or conference paper or conference proceeding or "conference review" or editorial or erratum or letter or note or report or "review" or short survey or trade journal) (522)
37 35 not 36 (629)
38 15 and 25 (718)
39 28 (143)

40 limit 39 to yr="2007 -Current" (97)
41 limit 40 to (book or book series or conference abstract or conference paper or conference proceeding or "conference review" or editorial or erratum or letter or note or short survey or trade journal) (18)
42 from 37 keep 1-629 (629)
43 40 not 41 (79)
44 37 (629)
45 from 44 keep 1-629 (629)

Database: Cochrane Library
Search Strategy:
'Fecal Incontinence'* in title, abstract, keyword
*automatically also searches for 'faecal incontinence'

AMED: Allied and Complementary Medicine

AMED-RCTs
1 meta analysis
2 meta-analysis
3 meta analys$.tw
4 meta-analys$.tw
5 (systematic adj (review$1 or overview$1).tw
6 Or/1-5
7 Cochrane.ab
8 Embase.ab
9 (psychlit or psyclit).ab
10 (psychinfor or psycinfo).ab
11 Or/7-10
12 Reference list$.ab
13 Bibliograph$.ab
14 Hand search.ab
15 Relevant journals.ab
16 Manual search$.ab
17 Or/12-16
18 Selection criteria.ab
19 Data extraction.ab
20 18 or 19
21 Comment.tw
22 Letter.tw
23 Editorial.tw
24 Animal/
25 Humans/
26 25 not (24 and 25)
27 21-23,26
28 6 or 11 or 17 or 20

29 28 not 27
30 Randomized controlled trial/
31 Randomized controlled trial.tw
32 Random allocation/
33 Double blind method/
34 Single blind method/
35 Controlled clinical trial.pt
36 Randomized controlled trial.pt
37 Multicenter study.pt
38 Clinical trial.pt
39 Exp clinical trials
40 Or 30-39
41 (clinical adj trial$).tw
42 (singl$ or doubl$ or treb$ or tripl$).tw
43 42 adj (blind$3 or mask$3).tw
44 Placebos/
45 Placebo$.tw
46 Randomly allocated.tw
47 (allocated adj2 random$).tw
48 Or/41-47
49 40 or 48
50 Case report.tw
51 Letter.tw
52 Letter.pt
53 50 or 51 or 52
54 49 not 53
55 Exp cohort studies/
56 Cohort$.tw
57 Controlled clinical trial.pt
58 Epidemiologic methods/
59 55 or 56 or 57 or 58
60 Exp Fecal Incontinence/
61 F?ecal incontin*.ti,ab
62 60 or 61
63 54 and 62

AMED Observational

1 meta analysis
2 meta-analysis
3 meta analys$.tw
4 meta-analys$.tw
5 (systematic adj (review$1 or overview$1).tw
6 Or/1-5
7 Cochrane.ab
8 Embase.ab
9 (psychlit or psyclit).ab

10 (psychinfor or psycinfo).ab
11 Or/7-10
12 Reference list$.ab
13 Bibliograph$.ab
14 Hand search.ab
15 Relevant journals.ab
16 Manual search$.ab
17 Or/12-16
18 Selection criteria.ab
19 Data extraction.ab
20 18 or 19
21 Comment.tw
22 Letter.tw
23 Editorial.tw
24 Animal/
25 Humans/
26 25 not (24 and 25)
27 21-23,26
28 6 or 11 or 17 or 20
29 28 not 27
30 epidemiologic studies.tw
31 exp cohort studies/
32 exp case control studies/
33 case control studies/
34 retrospective studies or prospective studies or follow up studies
35 longitudinal studies/
36 case control.tw
37 (cohort adj (study or studies)).tw
38 Contro*.tw
39 Cohort analy$.tw
40 (follow up adj (study or studies)).tw
41 (observational adj (study or studies)).tw
42 Longitudinal.tw
43 Or/30-42
44 Exp fecal incontinence
45 F?ecal incontin*.ti
46 44 or 45
47 29 or 43
48 46 and 47

PedRO

Search strategy: fecal incontinence or faecal incontinence

CINAHL: Cumulative Index to Nursing and Allied Health

Table B1. Search strings used in Cumulative Index to Nursing and Allied Health

#	Query	Limiters/Expanders	Last Run Via
S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Clinical Queries: Therapy - High Sensitivity Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S10	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Clinical Queries: Therapy - High Sensitivity Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S9	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Published Date: 19800101-20141231 Narrow by SubjectAge: - all adult Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Limiters - Published Date: 19800101-20141231 Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S6	TI anal and incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S5	TI faecal and incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S4	TI fecal and incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text

#	Query	Limiters/Expanders	Last Run Via
S3	Anal incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S2	(MH "Fecal Incontinence")	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
S1	fecal incontinence OR faecal incontinence	Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text

Appendix C. Excluded Studies

Not a Direct FI Treatment Study (n = 22)

1. Elsebae MM. A study of fecal incontinence in patients with chronic anal fissure: prospective, randomized, controlled trial of the extent of internal anal sphincter division during lateral sphincterotomy. World Journal of Surgery. 2007 Oct;31(10):2052-7. PMID 17665247.
2. Boccasanta P, Venturi M, Barbieri S, et al. Impact of new technologies on the clinical and functional outcome of Altemeier's procedure: a randomized, controlled trial. Diseases of the Colon & Rectum. 2006 May;49(5):652-60. PMID 16575620.
3. Zimmerman DD, Gosselink MP, Hop WC, et al. Impact of two different types of anal retractor on fecal continence after fistula repair: a prospective, randomized, clinical trial. Diseases of the Colon & Rectum. 2003 Dec;46(12):1674-9. PMID 14668594.
4. Ho YH, Seow-Choen F, Tan M. Colonic J-pouch function at six months versus straight coloanal anastomosis at two years: randomized controlled trial. World Journal of Surgery. 2001 Jul;25(7):876-81. PMID 11572027.
5. Ho YH, Yu S, Ang ES, et al. Small colonic J-pouch improves colonic retention of liquids--randomized, controlled trial with scintigraphy. Diseases of the Colon & Rectum. 2002 Jan;45(1):76-82. PMID 11786768.
6. Meyer S, Hohlfeld P, Achtari C, et al. Pelvic floor education after vaginal delivery. Obstetrics & Gynecology. 2001 May;97(5 Pt 1):673-7. PMID 11339914.
7. Chassagne P, Jego A, Gloc P, et al. Does treatment of constipation improve faecal incontinence in institutionalized elderly patients? Age & Ageing. 2000 Mar;29(2):159-64. PMID 10791451.
8. Ouslander JG, Simmons S, Schnelle J, et al. Effects of prompted voiding on fecal continence among nursing home residents. Journal of the American Geriatrics Society. 1996 Apr;44(4):424-8. PMID 8636590.
9. Deen KI, Grant E, Billingham C, et al. Abdominal resection rectopexy with pelvic floor repair versus perineal rectosigmoidectomy and pelvic floor repair for full-thickness rectal prolapse. British Journal of Surgery. 1994 Feb;81(2):302-4. PMID 8156369.
10. Miner PB, Donnelly TC, Read NW. Investigation of mode of action of biofeedback in treatment of fecal incontinence. Digestive Diseases & Sciences. 1990 Oct;35(10):1291-8. PMID 2209296.
11. Markland AD, Richter HE, Burgio KL, et al. Weight loss improves fecal incontinence severity in overweight and obese women with urinary incontinence. International Urogynecology Journal. 2011 Sep;22(9):1151-7. PMID 21567259.
12. Glazener CM, Herbison GP, MacArthur C, et al. Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up. BMJ. 2005 Feb 12;330(7487):337. PMID 15615766.
13. Glazener CM, Herbison GP, Wilson PD, et al. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. BMJ. 2001 Sep 15;323(7313):593-6. PMID 11557703.
14. Glazener CM, MacArthur C, Hagen S, et al. Twelve-year follow-up of conservative management of postnatal urinary and faecal incontinence and prolapse outcomes: randomised controlled trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2014 Jan;121(1):112-20. PMID 24148807.
15. Scaglia M, Delaini G, Destefano I, et al. Fecal incontinence treated with acupuncture - a pilot study. Autonomic Neuroscience: Basic and Clinical. 2009 28 Jan;145(1-2):89-92. PMID 2009022616.
16. Melenhorst J, Koch SM, Uludag O, et al. Is a morphologically intact anal sphincter necessary for success with sacral nerve modulation in patients with faecal incontinence? Colorectal Disease. 2008 Mar;10(3):257-62. PMID 17949447.

17. Chan MK, Tjandra JJ. Sacral nerve stimulation for fecal incontinence: external anal sphincter defect vs. intact anal sphincter. Diseases of the Colon & Rectum. 2008 Jul;51(7):1015-24; discussion 24-5. PMID 18484136.

18. Terra MP, Dobben AC, Berghmans B, et al. Electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence: a cohort study of 281 patients. Diseases of the Colon & Rectum. 2006 Aug;49(8):1149-59. PMID 16773492.

19. Allgayer H, Dietrich CF, Rohde W, et al. Prospective comparison of short- and long-term effects of pelvic floor exercise/biofeedback training in patients with fecal incontinence after surgery plus irradiation versus surgery alone for colorectal cancer: clinical, functional and endoscopic/endosonographic findings. Scandinavian Journal of Gastroenterology. 2005 Oct;40(10):1168-75. PMID 16165701.

20. Giordano P, Renzi A, Efron J, et al. Previous sphincter repair does not affect the outcome of repeat repair. Diseases of the Colon & Rectum. 2002 May;45(5):635-40. PMID 12004213.

21. Efron JE. The SECCA procedure: a new therapy for treatment of fecal incontinence. Surgical Technology International. 2004;13:107-10. PMID 15744681.

22. Jorge JM, Wexner SD, James K, et al. Recovery of anal sphincter function after the ileoanal reservoir procedure in patients over the age of fifty. Diseases of the Colon & Rectum. 1994 Oct;37(10):1002-5. PMID 7924704.

Off Topic (n = 8)

1. Matzel KE, Stadelmaier U, Hohenfellner M, et al. Chronic sacral spinal nerve stimulation for fecal incontinence: long-term results with foramen and cuff electrodes. Diseases of the Colon & Rectum. 2001 Jan;44(1):59-66. PMID 11805564.

2. Santoro GA, Eitan BZ, Pryde A, et al. Open study of low-dose amitriptyline in the treatment of patients with idiopathic fecal incontinence. Diseases of the Colon & Rectum. 2000 Dec;43(12):1676-81; discussion 81-2. PMID 11156450.

3. Miller R, Bartolo DC, Locke-Edmunds JC, et al. Prospective study of conservative and operative treatment for faecal incontinence. British Journal of Surgery. 1988 Feb;75(2):101-5. PMID 3349291.

4. Wexner SD, Hull T, Edden Y, et al. Infection rates in a large investigational trial of sacral nerve stimulation for fecal incontinence. Journal of Gastrointestinal Surgery. 2010 Jul;14(7):1081-9. PMID 20354809.

5. Poirier M, Abcarian H, Nelson R. Malone antegrade continent enema: an alternative to resection in severe defecation disorders. Diseases of the Colon & Rectum. 2007 Jan;50(1):22-8. PMID 17115341.

6. Takahashi T, Garcia-Osogobio S, Valdovinos MA, et al. Extended two-year results of radio-frequency energy delivery for the treatment of fecal incontinence (the Secca procedure). Diseases of the Colon & Rectum. 2003 Jun;46(6):711-5. PMID 12794570.

7. Riss S, Stift A, Teleky B, et al. Long-term anorectal and sexual function after overlapping anterior anal sphincter repair: A case-match study. Diseases of the Colon and Rectum. 2009 June;52(6):1095-100. PMID 2009402353.

8. Thomas GP, Norton C, Nicholls RJ, et al. A pilot study of transcutaneous sacral nerve stimulation for faecal incontinence. Colorectal Disease. 2013 November;15(11):1406-9. PMID 2013702071.

No Patient-Reported Outcomes/Data Not Usable (n = 20)

1. Bouguen G, Ropert A, Laine F, et al. Effects of transcutaneous tibial nerve stimulation on anorectal physiology in fecal incontinence: a double-blind placebo-controlled cross-over evaluation. Neurogastroenterology & Motility. 2014 Feb;26(2):247-54. PMID 24304363.
2. Bharucha AE, Edge J, Zinsmeister AR. Effect of nifedipine on anorectal sensorimotor functions in health and fecal incontinence. American Journal of Physiology - Gastrointestinal & Liver Physiology. 2011 Jul;301(1):G175-80. PMID 21493732.
3. Fox M, Stutz B, Menne D, et al. The effects of loperamide on continence problems and anorectal function in obese subjects taking orlistat. Digestive Diseases & Sciences. 2005 Sep;50(9):1576-83. PMID 16133954.
4. Cheetham MJ, Kamm MA, Phillips RK. Topical phenylephrine increases anal canal resting pressure in patients with faecal incontinence. Gut. 2001 Mar;48(3):356-9. PMID 11171825.
5. Vaizey CJ, Kamm MA, Roy AJ, et al. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. Diseases of the Colon & Rectum. 2000 Mar;43(3):298-302. PMID 10733109.
6. Heymen S, Pikarsky AJ, Weiss EG, et al. A prospective randomized trial comparing four biofeedback techniques for patients with faecal incontinence. Colorectal Disease. 2000;2(2):88-92. PMID 2001409335.
7. Deen KI, Kumar D, Williams JG, et al. Randomized trial of internal anal sphincter plication with pelvic floor repair for neuropathic fecal incontinence. Diseases of the Colon & Rectum. 1995 Jan;38(1):14-8. PMID 7813338.
8. Oya M, Ortiz J, Grant EA, et al. A video proctographic assessment of the changes in pelvic floor function following three forms of repair for post-obstetric neuropathic faecal incontinence. Digestive Surgery. 1994;11(1):20-4. PMID 1995007677.
9. Tobin GW, Brocklehurst JC. Faecal incontinence in residential homes for the elderly: prevalence, aetiology and management. Age & Ageing. 1986 Jan;15(1):41-6. PMID 3953330.
10. Latimer PR, Campbell D, Kasperski J. A components analysis of biofeedback in the treatment of fecal incontinence. Biofeedback & Self Regulation. 1984 Sep;9(3):311-24. PMID 6525357.
11. Harford WV, Krejs GJ, Santa Ana CA, et al. Acute effect of diphenoxylate with atropine (Lomotil) in patients with chronic diarrhea and fecal incontinence. Gastroenterology. 1980 Mar;78(3):440-3. PMID 7351282.
12. Collins E, Hibberts F, Lyons M, et al. Outcomes in non-surgical management for bowel dysfunction. British Journal of Nursing. 2014 Jul 24-Aug 13;23(14):776-80. PMID 25062312.
13. Oom DMJ, Steensma AB, Van Lanschot JJB, et al. Is sacral neuromodulation for fecal incontinence worthwhile in patients with associated pelvic floor injury? Diseases of the Colon and Rectum. 2010 April;53(4):422-7. PMID 2010271195.
14. Lacima G, Pera M, Amador A, et al. Long-term results of biofeedback treatment for faecal incontinence: a comparative study with untreated controls. Colorectal Disease. 2010 Aug;12(8):742-9. PMID 19486084.
15. Oberwalder M, Dinnewitzer A, Nogueras JJ, et al. Imbrication of the external anal sphincter may yield similar functional results as overlapping repair in selected patients. Colorectal Disease. 2008 Oct;10(8):800-4. PMID 18384424.
16. Rasmussen OO, Puggaard L, Christiansen J. Anal sphincter repair in patients with obstetric trauma: Age affects outcome. Diseases of the Colon and Rectum. 1999 February;42(2):193-5. PMID 1999066424.
17. Orrom WJ, Miller R, Cornes H, et al. Comparison of anterior sphincteroplasty and postanal repair in the treatment of idiopathic fecal incontinence. Diseases of the Colon & Rectum. 1991 Apr;34(4):305-10. PMID 2007347.
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Appendix D. Risk of Bias Assessment Forms

FI Randomized Controlled Trials

Author (year): **Title:**

Selection Bias	
Was method of randomization used to generate the sequence described in sufficient detail to assess whether it should produce comparable groups? (inadequate randomization?)	
Was method of treatment allocation adequate to keep treatment concealed until desired time? (inadequate allocation concealment)	
Were the groups similar at baseline regarding the most important prognostic indicators?	
Were all randomized participants analyzed in the group to which they were allocated?	
Risk of selection bias (inadequate randomization or allocation concealment):	**[Low, Unclear, High]**
Performance Bias	
Was the care provider blinded to the intervention?	Yes, No, NR
Were the participants blinded to the intervention?	Yes, No, NR
Nondrug interventions: Were interventions adequately defined so they could be replicated?	
Were co-interventions avoided? Differ by group?	
Was the intended blinding effective?	
Risk of performance bias due to lack of participant and personnel blinding, intervention definition & fidelity to treatment:	**[Low, Unclear, High]**
Detection Bias	
Were the outcome assessors blinded to the intervention?	Yes, No, NR, NA
Was the scale/tool used to measure outcomes validated, reliable?	
Was the timing of the outcome assessment similar in all groups?	
Were significance estimates for results appropriately corrected for multiple comparisons?	
Risk of detection bias due to lack of outcome assessor blinding, measurement of outcomes, statistical analysis:	**[Low, Unclear, High]**
Attrition Bias	
Was attrition lower than 20%? (Overall? By treatment group?)	Yes, No, NR, and %
Were reasons for incomplete/missing data adequately explained? (# assessed, dropped out, lost to followup)	
Was incomplete data handled appropriately?	
Risk of attrition bias due to amount, nature, or handling of incomplete outcome data?	**[Low, Unclear, High]**
Reporting Bias	
Were all outcomes in the Methods reported in Results or were only select outcomes reported?	
Were results (in tables and/or text) reported for all randomized patients for: Main outcomes? All outcomes? By treatment group?	
Risk of reporting bias due to selective outcome reporting?	**[Low, Unclear, High]**
Other Sources of Bias	
Are there other risks of bias? If yes, describe them	
Overall risk of bias assessment by outcome(s)	**[Low, Moderate or High] and explanation (1-2 sentences)**

NA=not applicable; NR=not reported

FI Observational Studies

Question	Response	Criteria	Justification
	Internal Validity		
1. Study design: prospective, retrospective, or mixed?	Prospective ☐	Outcome had not occurred when study was initiated; information was collected over time	
	Mixed ☐	One group was studied prospectively; other(s) retrospectively	
	Retrospective ☐	Analyzed data from past records, claims	
2. Were inclusion/ exclusion criteria clearly stated?	Yes ☐	Clearly stated	
	Partially ☐	Some, but not all criteria stated or some not clearly stated.	
	No ☐	Unclear	
3. Were baseline characteristics measured using valid and reliable measures and are they equivalent in both groups?	Yes ☐	Valid measures, groups ~ equivalent	
	No ☐	Nonvalidated measures or nonequivalent groups	
	Uncertain ☐	Could not be ascertained	
4. Were important variables known to impact the outcome(s) assessed at baseline?	Yes ☐	Yes, most or all known factors were assessed	
	No ☐	Critical factors are missing	
	Uncertain ☐		
5. Is the level of detail describing the intervention adequate?	Yes ☐	Intervention sufficiently described	
	Partially ☐	Some of the above features.	
	No ☐	Intervention poorly described	
6. Is the selection of the comparison group appropriate?	Yes ☐	Other adults with fecal incontinence with similar etiologic, demographic, severity and comorbid features	
	No ☐		
7. Was the impact of a concurrent intervention or an unintended exposure that might bias results isolated?	Yes ☐	By inclusion criteria, protocol, or other means	
	Partially ☐	Some were isolated, others were not	
	No ☐	Important concurrent interventions were not isolated or prohibited	
8. Were there attempts to balance the allocation across groups? (e.g., stratification, matching or propensity scores)	Yes ☐	(*If yes, what method was used?)*	
	No ☐		
	Uncertain ☐	Could not be ascertained	
9. Were outcomes assessors blinded?	Yes ☐	Who assessed outcomes?	
	No ☐		
	Uncertain ☐	Not reported	
10. Were outcomes assessed using valid and reliable measures, and used consistently across all study participants?	Yes ☐	Measures were valid and reliable (i.e., objective measure, validated scale/tool); consistent across groups	
	Partially ☐	Some of the above features	
	No ☐	None of the above features	
	Uncertain ☐	Could not be ascertained.	
11. Was length of followup the same for all groups?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained	
12. Did attrition result in differences in group characteristics between baseline and followup?	Yes ☐	*(If yes, for which followup period(s)?)*	
	No ☐		
	Uncertain ☐	Could not be ascertained	
13. If dissimilar baseline characteristics, does the analysis control for baseline differences between groups?	Yes ☐	What method?	
	No ☐		
	Uncertain ☐	Could not be ascertained	

Question	Response	Criteria	Justification
14. Were confounding and/or effect modifying variables assessed using valid and reliable measures across all study participants?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained (i.e., retrospective designs where eligible at baseline could not be determined)	
	NA ☐	No confounders or effect modifiers included in the study.	
15. Were important confounding and effect modifying variables taken into account in design and/or analysis? (e.g., matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment)	Yes ☐		
	Partially ☐	Some variables taken into account or adjustment achieved to some extent.	
	No ☐	Not accounted for or not identified.	
	Uncertain ☐	Could not be ascertained	
16. Are statistical methods used to assess the primary outcome appropriate to the data?	Yes ☐	Statistical techniques used must be appropriate to the data.	
	Partially ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained	
17. Is there suggestion of selective outcome reporting?	Yes ☐	Partial reporting of prespecified outcomes (e.g., secondary not primary outcomes; only significant outcomes; beneficial not adverse outcomes, etc.)	
	No ☐		
	Uncertain ☐	Could not be ascertained	
18. Was the funding source identified?	Yes ☐	Who provided funding?	
	No ☐		
	Uncertain ☐		
Overall assessment			
Overall Risk of Bias Assessment	Low ☐	Results are believable taking study limitations into consideration	
	Moderate ☐	Results are probably believable taking study limitations into consideration	
	High ☐	Results are uncertain taking study limitations into consideration	

FI= fecal incontinence

Appendix E. Common Fecal Incontinence Outcome Measures

Table E. Common fecal incontinence outcome measures

Measure	Description	Scoring Range/Items	Best Score	Minimal Clinically Important Difference (MID) (if known)	MID method(s)
Severity and impact					
Browning and Parks Incontinence Score[1]	Degree: 4 categories (A) continent for solid/liquid, B) continent for solid/liquid, not gas, C) continent for solid, not liquid/gas, D) incontinent for solid/liquid/gas)	A-D 4 items	A		
Cleveland Clinic Fecal Incontinence Score/Wexner (CCFIS)[2]	Frequency: 5 categories (low: <1/month to high: >1/day) Consistency: 3 categories (gas, liquid, solid) Pad use; Lifestyle alteration	0-20 5 items	0	-2 to -3 points[3]	Anchor-based
Fecal Incontinence and Continence Assessment (FICA)[4]	Frequency (low: ≤1/month to high: ≥2-3/week); Consistency/Amount (gas only/soiling, small amount of stool, moderate/large amount of stool); Pad use; Urgency	1-12 4 items	1		
Fecal Incontinence Severity Instrument (FISI)[5]	Frequency: 6 categories (low: 1-3/month to high:>2/day) Consistency: 4 categories (gas, liquid, solid, mucous)	0-61 4 items	0	-4 points[6]	Anchor- and distribution-based
Miller's Incontinence Score[7]	Frequency: 3 categories (low: <1/month to high: >1/week) Consistency: 3 categories (gas, liquid, solid)	0-18 3 items	0		
Pescatori Fecal Incontinence Score[8]	Frequency: 3 categories (occasionally, weekly, daily) Consistency: 3 categories (gas, liquid, solid)	0-6 3 items	0		
St. Mark's Fecal Incontinence Score[9]	Frequency: 4 categories (low: <1/month; high: most days); Consistency: 3 categories (gas, liquid, solid); Urgency; Difficulty cleaning; Soiling	0-13 6 items	0		
Vaizey Fecal Incontinence Score[10]	Frequency: 5 categories (low: 1/month; high: every day); Consistency: 3 categories (gas, liquid, solid); Pad use; Urgency; Lifestyle alterations; Antidiarrheal medication use	0-24 7 items	0	-5 points[11] -3 to -5 points[3]	Anchor- and distribution-based; Anchor-based
Quality of life					
American Medical Systems Fecal Incontinence Quality of Life Questionnaire[12]	Modification of FIQL[13] Physical impact, Psychological impact, Social impact, Pad use, Lifestyle alterations, Embarrassment/shame, Depression, Coping/Behavior	NR 39 items	NR		
Fecal Incontinence Quality of Life (FIQL) Scale[13]	4 scales (items): Lifestyle (10), Coping/Behavior (9), Depression/Self-Perception (7), Embarrassment (3) [Measure provides subscale scores (not overall)]	1-5 per item 29 items	5 (NA)	1.1 to 1.2 points[3] per subscale	Anchor-based

Best score= least impaired score possible in scale.

CCFIS=Cleveland Clinic Florida Fecal Incontinence Score; FI=Fecal Incontinence; FIQL=Fecal Incontinence Quality of Life; FISI=Fecal Incontinence Severity Score; GPE=Global Perceived Effect; ICIQ-BS=International Consultation Incontinence Questionnaire Bowel Symptoms; NA=not applicable; NR=not reported; SF-36=Short Form Health Survey

Appendix F. Evidence Tables

Table F1. Patient-reported outcomes used in fecal incontinence randomized controlled trials

Measure	Studies in Which Outcome Was Used
Severity and Impact of FI and bowel issues	
Ability to safely release gas	Hallgren, 1994[14]
Adequate relief (yes or no)	Heymen, 2009[15]
Appropriate fecal and urine toileting ratio	Schnelle, 2002[16]
Appropriate toileting ratio	Schnelle, 2010[17]
Bowel function	Christensen, 2006[18]
Bowel habits (scale not specified)	Schwander, 2011;[19] Bliss, 2001;[20] Yoshioka, 1999;[21] Palmer, 1980[22]
Bowel movements during day	Hallgren, 1994[14]
Bowel movements over 3 weeks	Duelund-Jakobsen, 2012;[23] Michelsen, 2008[24]
Bowel movements over a mean of 3 days	Kusunoki, 1990[25]
Bowel movements per day	Bartlett, 2011;[26] Schnelle, 2010;[17] Sun, 1997;[27] Hallgren, 1994[14]
Bowel movements per week	Leroi, 2005;[28] Osterberg, 2004;[29] Read, 1982[30]
Bowel openings over 3 weeks	Duelund-Jakobsen, 2013[31]
Bowel symptom questionnaire[32]	Norton, 2003[33]
Browning & Parks Incontinence Score[1]	van Tets, 1998[34]
Cleveland Clinic Constipation Score[35] (0-30)	Christensen, 2006[18]
Cleveland Clinic Fecal Incontinence Score (CCFIS)[2]	Thin, 2015;[36] Damon, 2014;[37] Duelund-Jakobsen, 2013;[31] Morris, 2013;[38] Duelund-Jakobsen, 2012;[23] Pinedo, 2012;[39] Bartlett, 2011;[26] Graf, 2011;[40]Schwander, 2011;[19] Schwander, 2010;[41] Pinedo, 2009;[42] Tjandra, 2009;[43] Michelsen, 2008;[24] Tjandra, 2008;[44] Naimy, 2007;[45] Healy, 2006;[46] Leroi, 2005;[28] Davis, 2004;[47] Mahoney, 2004;[48] O'Brien, 2004;[49] Hasegawa, 2000;[50] Yoshioka, 1999[21]
Complete fecal continence	Deen, 1993[51]
Complete responders to treatment (percent with no FI for one month)	Schwander, 2011;[19] Schwander, 2010[41]
Duration of bowel management	Coggrave, 2010[52]
Extent of FI (11-point scale, 0-10; 0=best score)	Deen, 1993[51]
Fecal continence grade (I: flatus II: liquid stool III: solid stool)	Schwander, 2011[19]
Fecal soiling (scale not specified)	Yoshioka, 1999[21]
Fecal urgency (ability to reach toilet: "none of the time" "little of the time" "some of the time" "all of the time")	Bartlett, 2011[26]
Fecal urgency (scale not specified)	Leroi, 2005;[28] Yoshioka, 1999[21]
Fecal urgency: days with urgency over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Fecal urgency: deferring time (visual analogue scale)	Osterberg, 2004[29]
Fecal urgency: delay for postponing defecation (range: less than 5 minutes to more than 15 minutes)	Leroi, 2005[28]
Fecal urgency: episodes per week	Read, 1982[30]
Fecal urgency: episodes over 3 weeks	Michelsen, 2008[24]
Fecal urgency: stools with urgency over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Fecal urgency: rectal urgency (proportion bowel movements preceded by urgency)	Bharucha, 2014[53]
Fecal urgency: time denominator not specified	Sun, 1997[27]
FI episodes: amount ("none" "leakage between buttocks" "on an incontinence absorbent product" "on underwear" "on outerwear" "on shoes/the floor")	Bliss, 2014[54]

Measure	Studies in Which Outcome Was Used
FI episodes: change from baseline in number of incontinence-free days	Graf, 2011[40]
FI episodes: days with FI	Bharucha, 2014[53]
FI episodes: days with FI per week	Tjandra, 2008[44]
FI episodes: days with soiling over 3 weeks	Michelsen, 2008[24]
FI episodes: days with staining per week	Tjandra, 2008[44]
FI episodes: days with pads per week	Tjandra, 2008[44]
FI episodes: FI episodes per day	Bharucha, 2014;[53] Bliss, 2014;[54] Schnelle, 2010[17]
FI episodes: FI episodes per week	Thin, 2015;[36] Tjandra, 2008;[44] Ilnyckyj, 2005;[55] Leroi, 2005;[28] Whitehead, 1985;[56] Read, 1982[30]
FI episodes: FI episodes per 2 weeks	Graf, 2011[40]
FI episodes: FI episodes per 3 weeks	Duelund-Jakobsen, 2013;[31] Michelsen, 2008[24]
FI episodes: FI episodes per month	Deen, 1993[51]
FI episodes: need for night evacuations	Hallgren, 1994[14]
FI episodes: % of daily checks with FI during 1 month	Schnelle, 2002[16]
FI episodes: % incontinent stools over 8 days	Bliss, 2001[20]
FI episodes: % unformed stools per week	Read, 1982[30]
FI episodes: total incontinence over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
FI episodes: passive incontinence over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
FI episodes: urgency incontinence over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
FI episodes: time denominator not specified	Coggrave, 2010;[52] Sun, 1997[27]
FI subscale of Fecal Incontinence and Continence Assessment (FICA)[4]	Bharucha, 2014[53]
Fecal Incontinence Severity Instrument (FISI)[5]	Bharucha, 2014;[53] Heymen, 2009;[15] Lauti, 2008;[57] Park, 2007[58]
Frequency of side effects	Park, 2007[58]
GI Symptom Rating Scale for IBS	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Impact on daily activities	Christensen, 2006[18]
Improved in grade or frequency of FI (%)	Schwander, 2011;[19] Schwander, 2010[41]
International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF)	Schwander, 2011[19]
Investigator-rated severity (11-point scale, 0-10; 0=no incontinence problems)	Solomon, 2003[59]
Knowles-Eccersley-Scott-Symptom (KESS) questionnaire for constipation	Damon, 2014[37]
Level of stepwise intervention at which evacuation began	Coggrave, 2010[52]
Level of stepwise intervention required to complete evacuation	Coggrave, 2010[52]
Miller's Incontinence Score[7]	Osterberg, 2004[29]
Neurogenic Bowel Dysfunction Score[60]	Christensen, 2006 [18]
Number asymptomatic for FI after therapy	Fynes, 1999[61]
Overall FI symptom score (0-10 per day over 28 days; 0=no symptoms, 280=maximum symptoms)	Carapeti, 2000[62]
Pad days over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Pad use (yes or no)	Osterberg, 2004[29]
Pad use: during daytime	Hallgren, 1994[14]
Pad use: during nighttime	Hallgren, 1994[14]
Patient-rated achievement of therapeutic goals (6-point scale; 1=very good, 6=unsatisfactory)	Schwander, 2011[19]
Patient assessment of improvement ("good" "fair" "poor")	Yoshioka, 1999[21]
Patient-rated bowel control (11-point scale, 0-10; 0=no control)	Bartlett, 2011;[26] Norton, 2006[63]

Measure	Studies in Which Outcome Was Used
Patient-rated effect of symptoms on life (4-point scale; “not at all” “a little” “quite a lot” “a great deal”)	Norton, 2006[63]
Patient-rated effect of treatment (11-point scale, 0-10; 0=no effect)	Naimy, 2007[45]
Patient-rated improvement (estimated percent of overall improvement or deteriorating of symptoms during treatment)	Carapeti, 2000;[62] Carapeti, 2000[64]
Patient-rated severity (11-point scale, 0-10; 0=no incontinence problems)	Solomon, 2003[59]
Patient-rated symptom change (11-point scale, -5 to +5; -5=significant aggravation, +5=significant improvement)	Norton, 2006[63]
Patient-rated treatment effectiveness (“worse” “same” “improved” “cured”) and rating of this change (11-point scale, -5 to +5; -5=significant aggravation, +5=significant improvement)	Damon, 2014;[37] Norton, 2003[33]
Patient satisfaction (100mm visual analogue scale; “not at all” – “completely satisfied”)	Bharucha, 2014[53]
Patient satisfaction (11-point scale, 0-10; 0=very dissatisfied	Norton, 2006;[63] Davis, 2004[47]
Patient satisfaction (11-point scale, 0-10; 0=excellent function)	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Perianal skin trouble (yes or no)	Kusunoki, 1990[25]
Pescatori Fecal Incontinence Score[8]	Solomon, 2003;[59] Fynes, 1999[61]
Response to treatment (reduction in number of episodes across 2 weeks by 50% or more)	Graf, 2011[40]
Severity of abdominal pain: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of diarrhea: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of FI urgency: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of FI (authors’ own calculation)	Bliss, 2014[54]
Severity of FI: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of FI urgency (“mild” “moderate” “severe”)	Sun, 1997[27]
Severity of FI urgency: VAS (100mm; 0=absent)	Sun, 1997[27]
Severity of side effects	Park, 2007[58]
Side effects	Palmer, 1980[22]
Soiling (yes or no)	Kusunoki, 1990[25]
Soiling days over 3 weeks	Duelund-Jakobsen, 2013;[31] Duelund-Jakobsen, 2012[23]
Soiling during daytime	Hallgren, 1994[14]
Soiling during nighttime	Hallgren, 1994[14]
St. Mark’s Fecal Incontinence Score (0-13)[9]	Solomon, 2003[59]
Stool consistency (“formed” or “unformed”)	Sun, 1997[27]
Stool consistency (”liquid” “uniformed/loose” “soft/formed” or “hard/formed”)	Bliss, 2001[20]
Stool consistency (“solid” “loose” or “watery”)	Palmer, 1980[22]
Time to stool	Coggrave, 2010[52]
Vaizey Incontinence Score[10]	Dehli, 2013;[65]* Duelund-Jakobsen, 2013;[31]* Bols, 2012;[66] Duelund-Jakobsen, 2012;[23]* Schwander, 2011;[19] Schwander, 2010;[41] Christensen, 2006;[18] Michelsen, 2008;[24]* Carapeti, 2000;[62] Carapeti, 2000[64]
Quality of Life	
American Medical Systems Quality of Life Scale (AMS QoL; 39-items)[12]	O’Brien, 2004[49]

Measure	Studies in Which Outcome Was Used
Quality of Life Measure for individually-selected objectives (11-point scale, 0-10; 0=no QoL, 10= full QoL)	Solomon, 2003[59]
Euro-QoL 5D (EQ-5D)	Thin, 2015;[36] Dehli 2013[65]
Fecal Incontinence Quality of Life (FIQL) Scale[13]	Bharucha, 2014;[53] Damon, 2014;[37] Leroi, 2005;[28] Duelund-Jakobsen, 2013;[31] Bols, 2012;[66] Duelund-Jakobsen, 2012;[23] Pinedo, 2012;[39] Bartlett, 2011;[26] Graf, 2011;[40] Schwander, 2011;[19] Schwander, 2010;[41] Heymen, 2009;[15] Pinedo, 2009;[42] Tjandra, 2009;[43] Lauti, 2008;[57] Tjandra, 2008;[44] Naimy, 2007;[45] Park, 2007;[58] Christensen, 2006[18] (modified); Davis, 2004;[47] Mahoney, 2004[48]
Reduced quality of life (11-point scale, 0-10; 0=normal)	Naimy, 2007[45]
Unpublished FI-specific quality of life measure	Norton 2003[33]
Health Status	
Physical handicap (yes or no)	Osterberg, 2004[29]
Medical Outcomes Survey 36-item health survey (SF-36)[67]	Thin, 2015;[36] Morris, 2013;[38] Lauti, 2008;[57] Healy, 2006;[46] O'Brien, 2004;[49] Norton, 2003[33]
Medical Outcomes Survey 12-item health survey (SF-12)	Damon, 2014;[37] Tjandra, 2009;[43] Tjandra, 2008[44]
Social handicap (yes or no)	Osterberg, 2004[29]
Other	
Antidiarrheal medication use (type, dosages)	Bliss, 2001[20]
Attitudes Towards Treatment (ATT)	Heymen, 2009[15]
Beck Depression Inventory (BDI)	Heymen, 2009;[15] O'Brien, 2004[49]
Capsule consumption	Palmer, 1980[22]
Dietary intake	Bliss, 2001[20]
Global efficacy question (scale NR)	Park, 2007[58]
Global Perceived Effect (GPE; scale 1-9)	Bols, 2012[66]
Hospital Anxiety and Depression Scale (HAD)	Norton, 2003;[33] Carapeti 2000[64]
Loperamide use (% days)	Bharucha, 2014[53]
Medication use: stool regulation	Schwander, 2011[19]
Satisfaction with treatment	Christensen, 2006[18]
Spielberger State-Trait Anxiety Inventory (STAI-1 and STAI-2)	Heymen, 2009[15]

*Article states St. Mark's Fecal Incontinence Score was used; however, authors cited Vaizey, 1999[10]

Table F2. KQ 1: Fecal incontinence randomized controlled trial outcomes overview by treatment and followup duration

Treatment	Author, Year	FI Etiology	Followup*	FI Count	CCFIS	FISI	Vaizey	FIQL	Inter-mediate	Other
Nonsurgical										
Dietary fiber	Bliss, 2014[54]	NR	ST	X				X	X	FI amount and severity
Dietary fiber	Bliss, 2001[20]	NR	ST	X						Stool freq and consistency, antidiarrheal use, diet
Fiber + loperamide	Lauti, 2008[57]	Mixed	ST, IT			X		X		SF-36
Topical phenylephrine	Park, 2007[58]	Structural	ST			X		X		Side effects freq and severity, global efficacy question
Topical phenylephrine	Carapeti, 2000[64]	NR	ST				X		X	HAD, pt-rated improvement
Topical phenylephrine	Carapeti, 2000[62]	Structural	ST				X		X	Overall FI symptoms score, pt-rated improvement
Loperamide	Sun, 1997[27]	Mixed	ST	X					X	Stool freq; FI urgency, amount, severity; diarrhea, abdominal pain
Loperamide	Hallgren, 1994[14]	Structural	ST	X					X	Defecation freq, need for night evacuation, soiling, pad use, safe gas release
Loperamide	Read, 1982[30]	Mixed	ST	X					X	Stool freq, urgency episodes, unformed stools
Mixed antidiarrheal drugs	Palmer, 1980[22]	Mixed	ST	X						Stool freq, consistency, urgency, capsule consumption
Clonidine	Bharucha, 2014[53]	Mixed	ST	X		X		X	X	FICA, rectal urgency, pt satisfaction, loperamide use
Topical zinc-aluminum ointment	Pinedo, 2012[39]	NR	ST		X			X		
Topical estrogen	Pinedo, 2009[42]	Structural	ST		X			X		
Sodium valproate	Kusunoki, 1990[25]	Structural	ST						X	Stool freq, perianal skin trouble, soiling
PFMT-BF	Damon, 2014[37]	Mixed	IT		X			X	X	KESS, SF-12, pt-rated change and treatment effectiveness
PFMT-BF	Norton, 2003[33]	Mixed	LT						X	SF-36, HAD, bowel symptom questionnaire, pt-rated change and treatment effectiveness, unpublished FI-specific QoL measure
PFMT-BF	Heymen, 2009[15]	Mixed	IT, LT			X		X		Adequate relief, ATT, BDI, STAI-1, STAI-2
PFMT-BF	Whitehead, 1985[56]	Mixed	ST, LT	X					X	
PFMT-BF	Ilnyckyj, 2005[55]	NR	ST	X					X	
PFMT-BF	Bols, 2012[66]	Mixed	ST				X	X	X	GPE

Treatment	Author, Year	FI Etiology	Followup*	FI Count	CCFIS	FISI	Vaizey	FIQL	Inter-mediate	Other
PFMT-BF	Solomon, 2003[59]	Neurogenic	IT						X	SMFIS, Pescatori, investigator- and pt-rated severity, QoL measure for personal goals
PFMT-BF exercise	Bartlett, 2011[26]	Mixed	ST, LT		X			X	X	Bowel movements per day, urgency, pt-rated bowel control
PFMT-BF estim	Schwandner, 2011[19]	Mixed	IT, LT		X		X	X	X	ICIQ-SF, stool freq, % complete responders, FI grade, % improved in FI, goal achievement, medications
PFMT-BF estim	Schwandner, 2010[41]	Mixed	LT		X		X	X		Complete responders to treatment, improved in grade or freq of FI
PFMT-BF +/- estim	Naimey, 2007[45]	Structural	ST		X			X		Pt-rated effect of treatment, reduced QoL
PFMT-BF +/- estim	Mahoney, 2004[48]	Mixed	IT		X			X	X	
PFMT-BF +/- estim	Fynes, 1999[61]	Structural	IT						X	Pescatori, number asymptomatic
Electrostimulation	Norton, 2006[63]	Mixed	ST						X	Pt-rated: bowel control, effect on life, symptom change; pt satisfaction
Electrostimulation	Healy, 2006[46]	NR	IT		X				X	SF-36
Transanal irrigation	Christensen, 2006[18]	Neurogenic	ST				X	X		CCCS, bowel function, impact on daily activities, NBDS, treatment satisfaction
Stepwise bowel management intervention	Coggrave, 2010[52]	Spinal cord injury	ST	X						Duration and level of intervention, time to stool, minimum effective intervention
Exercise + diet	Schnelle, 2010[17]	NR	ST						X	Bowel movements, appropriate toileting ratio
Exercise + incontinence care	Schnelle, 2002[16]	NR	ST, LT	X						Appropriate fecal and urine toileting ratio
Dextranomer	Dehli, 2013[65]	Mixed	IT, LT				X		X	EQ-5D
Dextranomer	Graf, 2011[40]	Mixed	IT, LT	X	X			X		AE, response to treatment
Durasphere**	Morris, 2013[38]	NR	ST, LT		X				X	SF-36
Durasphere**	Tjandra, 2009[43]	Mixed	ST, LT		X			X	X	SF-12
PTNS vs. SNS	Thin, 2015[36]	Mixed	IT	X	X					SF-36, EQ-5D
Surgical										
Anal sphincter repair +/- BF	Davis, 2004[47]	Structural	IT, LT		X			X	X	Pt satisfaction
Anal sphincter repair	Hasegewa, 2000[50]	Structural	LT		X				X	

Treatment	Author, Year	FI Etiology	Followup*	FI Count	CCFIS	FISI	Vaizey	FIQL	Inter-mediate	Other
Artificial bowel sphincter	O'Brien, 2004[49]	Mixed	IT, LT		X				X	AMS QoL, SF-36, BDI
Gluteus maximus transposition vs. total pelvic floor repair	Yoshioka, 1999[21]	Neurogenic	LT		X				X	Bowel habits, fecal soiling, fecal urgency, pt-assessed improvement
Anterior levatorplasty vs. overlapping sphincteroplasty	Osterberg, 2004[29]	Neurogenic	IT, LT							Miller, stool freq, deferring time, pad use, physical and social handicap
Total pelvic floor repair vs. postanal repair	van Tets, 1998[34]	Neurogenic	IT						X	Browning & Parks Incontinence Score
Total pelvic floor repair vs. anterior levatorplasty vs. postanal repair	Deen, 1993[51]	Neurogenic	LT	X					X	Complete continence, extent of FI
SNS	Duelund-Jakobsen, 2013[31]	Mixed	ST	X	X		X	X	X	GSRS-IBS, bowel openings, days and stools with urgency, pad use, satisfaction, soiling days
SNS	Duelund-Jakobsen, 2012[23]	Mixed	IT	X	X		X	X	X	GSRS-IBS, bowel movements, days and stools with urgency, pad days, pt satisfaction, soiling days
SNS	Tjandra, 2008[44]	Mixed	IT, LT	X	X			X	X	SF-12
SNS	Michelsen, 2008[24]	Mixed	ST	X	X		X			Stool freq, episodes with urgency
SNS	Leroi, 2005[28]	Mixed	ST	X	X			X	X	Bowel movements, urgency, delay for postponing defecation
TOTAL	**50**			**19**	**22**	**4**	**10**	**22**	**34**	

*Followup length: ST= <3 mo; IT= 3 mo-6 mo; LT= >6 mo **Off-label & only 1 arm (Durasphere) was FDA approved

+/-=with or without; AE=Adverse Effects; AMS=American Medical System; ATT=Attitudes Towards Treatment; BDI=Beck Depression Inventory; BF=biofeedback; CCCS=Cleveland Clinic Constipation Score; CCFIS=Cleveland Clinic Fecal Incontinence Score; EQ-5D=EuroQoL Questionnaire-5 Dimensions; estim=electrostimulation; FDA=Food and Drug Administration; FI=Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life Scale; FISI=Fecal Incontinence Severity Index; freq=frequency; FU=Followup; GSRS-IBS=Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome; HAD=Hospital Anxiety and Depression Scale; IBS=irritable bowel syndrome; IT=intermediate-term; KESS= Knowles-Eccersley-Scott-Symptom questionnaire for constipation; LT=long-term; Miller=Miller's Incontinence Score; mo=month; NBDS=neurogenic bowel dysfunction score; Pescatori=Pescatori Fecal Incontinence Score; PFMT=Pelvic floor muscle training; pt=patient; QoL=Quality of Life; SNS=Sacral neurostimulation; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SMFIS=St. Mark's Fecal Incontinence Score; SNS=sacral nerve stimulation; ST=short-term; STAI=State-Trait Anxiety Inventory; Vaizey=Vaizey Incontinence Score; VAS=Visual Analogue Scale

Table F3. KQ 1: Distribution of treatments by FI etiology in randomized controlled trials

Treatments	Structural	Neurogenic	Mixed	Unknown or Not Reported	Row Total
Nonsurgical					
Dietary fiber supplements				2[20, 54]	2
Antidiarrheal drug plus fiber supplement			1[57]		1
Topical phenylephrine (sphincter function enhancement drug)	2[58, 62]			1[64]	3
Antidiarrheal drugs	1[14]		3[22, 27, 30]		4
Other drugs	2[25, 42]		1[53]	1[39]	4
PFMT+/- biofeedback		1[59]	6[15, 26, 33, 37, 56, 66]	1[55]	8
PFMT-BF +/- electrostimulation	2[45, 61]		3[19, 41, 48]		5
Electrostimulation			1[63]	1[46]	2
Rectal irrigation		1 SCI[18]			1
Multicomponent intervention		1 SCI[52]		2 NH[16, 17]	3
Tissue-bulking injections			3[40, 43, 65]*	1[38]*	4*
PTNS			1[36]		1
Surgical					
Anal sphincter repair (sphincteroplasty)	1[50]				1
Anal sphincter repair +/- Biofeedback	1[47]				1
Anal sphincter replacement		1[21]	1[49]		2
Other surgeries		2[34, 51]			2
Surgery vs. nonsurgical treatment				1[29]	1
Sacral neurostimulation			5[23, 24, 28, 31, 44]		5
Column Total	9	6	25	10	50

+/-=with or without; BF= biofeedback; NH=nursing home residents; PFMT=pelvic floor muscle training; PTNS=percutaneous posterior tibial nerve stimulation; SCI=adults with spinal cord injury

* Only 1 arm was FDA-approved (off-label Durasphere)

Table F4. KQ 1: Surgical treatments for fecal incontinence: randomized controlled trials and quality ratings

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (Benefits)*	Risk of Bias (Inverse of Quality)
Anal sphincter repair						
Davis, 2004[47]	Is adjuvant biofeedback after anal sphincter repair superior to sphincter repair alone?	N=38 n=31 100% F: 60 yr Structural T: surgery; BF duration NR FU: 3mo, 6mo, 1 yr	**T**: Anal sphincter repair + adjuvant biofeedback starting 3 mo post-surgery (18) **C**: Anal sphincter repair (20)	**CCFIS, patient satisfaction**, FIQL	At 1 y post-surgery (9 mo. after BF initiation), differences in change in CCFIS (-5.8 points treated vs. -4.1 points control), pt. satisfaction and FIQL component scores were not significant. Overall FIQL not reported. Power not reported. Excluded post-randomization data on 18% of sample.	High
Hasegawa, 2000[50]	Is anal sphincter repair with fecal diversion superior to sphincter repair?	N=27 n=27 96% F; 46 yr Mixed T: surgery FU: mean 34mo	**T**: Anal sphincter repair + stoma (fecal diversion) (13) **C**: Anal sphincter repair (14)	**CCFIS**	Statistical test of difference in scores at followup only: mean CCFIS improved 5.7 points in stoma group vs. 4.4 in controls. Power not reported. Trial stopped early due to high rate of complications, and no treatment advantage	High
Anal sphincter replacement						
O'Brien, 2004[49]	Effectiveness of artificial bowel sphincter (ABS) vs. conservative management for severe FI	N=14 n=13 93% F; 63 yr Mixed T: surgery FU: 3 mo, 6 mo	**T**: Artificial Bowel Sphincter (Action Neo-sphincter®) (7) **C**: Conservative medical management (7)	**CCFIS**, SF-36, AMS QoL scale, BDI	Statistical test is of difference in scores at followup not change from baseline. Excluding one patient with a surgical failure that required colostomy and two colostomy revisions, greater CCFIS improvement noted in treated vs. controls at 6 mo (14 vs. 3 points); 3 mo not reported. Significant improvement in AMS-QoL, SF-36 (mental) with surgery; no difference in BDI, SF-36 (physical). Underpowered study.	High
Other surgeries						
Yoshioka, 1999[21]	Compare total pelvic floor repair (TPFR) vs. gluteus maximus (GMT) transposition (without e-stim) (GMT) for postobstetric	N=24 n=24 100% F; 60 yr Obstetric: intact sphincter T: surgery FU: 18 mo.	**T_1**: Total pelvic floor repair (TPFR) (12) **T_2**: GMT without electrical stimulation (12)	CCFIS, self-rated improvement, bowel habit, rectal evacuation, fecal urgency, fecal soiling	Within-group analysis at 18 mo: Same CCFIS improvement (6.1 points) and "good" functional result rating (7 of 12 patients) both groups. No difference in bowel habit, urgency or soiling by group. No power calculation. Authors report limited experience with GMT.	Moderate

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (Benefits)*	Risk of Bias (Inverse of Quality)
	neuropathic FI					
van Tets, 1998[34]	Effectiveness of postanal repair vs. total pelvic floor repair (TPFR) for neurogenic FI	N=20 n=20 100% F; 55 yr Neurogenic T: surgery FU: 3 mo	T_1: Postanal repair (11) T_2: Total pelvic floor repair (TPFR) (9)	Browning & Parks Incontinence Score	At 3 mo, 45% in postanal repair group reported improvement vs. 33% in TPFR group. No statistical comparison of patient-reported outcome measure. Power not reported.	Moderate
Deen, 1993[51]	Compare effectiveness of total pelvic floor repair (TPFR) vs anterior levatorplasy vs. postanal repair for neurogenic FI	N=36 n=20 100% F; 51 yr Neurogenic T: surgery FU: 6 mo, 2 yr	T_1: Total pelvic floor repair (TPFR) (12) T_2: Anterior levatorplasty (12) C: Postanal repair (12)	Complete Continence, FI freq per month extent of FI (0-10)	33% in anterior levatorplasty & 42% in postanal repair reported complete continence. Multiple between-group comparisons reported. FI freq not reported at 6 mo. At 2 y, median (range) FI freq per month was 2 (0-12) for TPFR, 5 (0-30) for anterior levatorplasty, and 10 (0-30) for postanal repair; only comparisons reported are of scores at followup and not of differences from baseline. Data on degree of FI not usable. Power not reported.	High
Surgical vs. nonsurgical						
Osterberg, 2004[29]	Compare levatorplasty vs. anal plug electro-stimulation for neurogenic FI	N=70 n=59 88% F; 66 yr neurogenic T: 1 d-5 wk FU: 3 m, 1 yr, 2 yr after treatment completion	T_1: Anterior levatorplasty (31) T_2: Anal plug electrostimulation: 12 sessions (20 min each) with therapist over 4-5 weeks. (28)	Miller's Incontinence score (0-18), stool freq, pad use, physical & social handicap, deferring time	No statistical comparison of between group differences at any time point for any outcome (within group change from baseline only). Miller's Incontinence score improved 6-7 points with surgery, which was 2-2.5 points more than anal plug e-stim improvements at 3 m, 1 yr and 2 yr. Stool freq. did not change in either group. Pad use decreased in both groups; physical and social handicap and deferring times improved with surgery. Underpowered study. Excluded post-randomization data on 16% of sample.	High
Surgically-implanted sacral neurostimulation (SNS)						
Duelund-Jakobsen, 2013[31]	Determine whether stimulation at 75% and 50% of	N=19 n=17 (3 mo.) 95% F; 60 yr Mixed	Crossover. Wash-out wk 1 of 4 wk trmt T_1: Stimulation at	FI freq, bowel habits, CCFIS, Vaizey, GSRS-IBS, FIQL, patient	Improvement in mean FI freq. did not differ significantly across ST settings. Mean change in CCFIS, Vaizey score, bowel habits, GSRS-IBS and pt	Moderate

Author, Year	Study Aim	N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Results (Benefits)*	Risk of Bias (Inverse of Quality)
	the sensory threshold (ST) is as effective as stimulation at ST in pts receiving SNS for FI	T: 3 x 4 wks FU:1 mo., 2 mo., 3 mo.	ST (19) T_2: Stimulation at 75% of ST (19) T_3: Stimulation at 50% of ST (19)	satisfaction	satisfaction did not differ significantly across settings. Coping subscale of FIQL improved in ST and 50% of ST groups vs 75% of ST over study period, but no additional significant changes in other FIQL subscales. Power not reported. Excluded 11% from 3 mo. analysis.	
Duelund-Jakobsen, 2012[23]	Which of 5 SNS settings restores efficacy in adults with existing SNS and sustained loss of efficacy?	N=15 n=15 % F: NR; 54 yr Mixed T: 5 x 4 wks FU: 20 wks; 11 unblinded for 12 more wks at chosen SNS setting	Crossover T_1- T_5: test 5 SNS stimulator settings (4 wks each), then unblinded and observed for 12 more wks) at preferred setting	FIQL, CCFIS, bowel diary with FI episodes, Vaizey, GSRS-IBS, patient satisfaction	Bowel diary scores including FI episodes significantly improved with high-frequency stimulation and low and prolonged pulse width; FIQL embarrassment improved at 2 settings. No significant differences in any other outcomes between settings at 20 wk. Improvement sustained at 32 wk (excluding data from 4 subjects). 8 of 11 satisfied with treatment. Sparse sample information; only mean age, years of FI in text.	High
Tjandra, 2008[44]	Is SNS better than best supportive care for FI?	N=120 n=113 (7 failed test SNS) 93% F; 63 yr Mixed T: 1 d up to 1 yr FU: 3 m, 6 m, 1 yr	T: SNS (single surgeon) plus 3 stimulator adjust-ments/1 yr. (53) C: Diet, oral bulking agents, PFMT; met with pelvic floor team 12-18x/1 yr	CCFIS, FI episodes, FI days/wk (bowel diary), FIQL, SF-12	Between-group differences in changes from baseline not reported; results are within-group changes from baseline. Significant decrease in CCFIS (-14.8 points), mean FI episodes (9.5 to 3.1), days of FI/wk (3.3 to 1), and all FIQL domains with SNS. Control CCFIS improved at 3 mo. only; controls had no significant improvement in other outcomes. No power calculation; adjusted for multiple comparisons.	Moderate
Michelson, 2008[24]	Does switching off SNS stimulator at night affect FI in adults with existing SNS?	N=20 n=19 95% F; 59 yr Mixed T: 3 wks. each FU: 6 wks: outcomes assessed	Crossover, no washout T1: SNS on 24 hr/d x 7 d/wk for 3 wks T2: SNS off at night for 3 wks	CCFIS, Vaizey, defecation frequency, urge episodes, liquid + solid episodes, days with soling	No base values reported for any measures. Median CCFIS and Vaizey increased (worse) by 1 point during OFF at night period. Days with soiling increased by 1; urge episodes unchanged. Power not reported.	High

Author, Year	**Study Aim**	**N Randomized, n Analyzed; % Female; Mean Age; FI Etiology; Treatment and Followup Duration**	**Study Groups** (n per group)	**Patient-Reported Outcomes** (primary outcome **bolded** if known)	**Reported Results (Benefits)***	**Risk of Bias (Inverse of Quality)**
		after both periods only				
Leroi, 2005[28]	Effectiveness of SNS with stimulation ON vs. OFF for FI in new SNS recipients (1-3 mo after SNS implantation)	N=34 pts n=24 91% F; 57 yr Mixed T: 1 mo x 2 FU: 1 mo, 2 mo	Crossover, no washout T_1: Stimulation ON (27) T_2: Stimulation OFF (27)	FI count, CCFIS, FIQL, urgency episodes, postponing defecation, bowel movements	Median improvement in CCFIS 2 points greater in stimulation ON vs OFF period (1 mo), but difference not significant. Authors report statistically significant improvement in median FI count, but data in graph & not usable. No significant changes in urgency episodes, delay in postponing defecation, and number of BM per week between groups at 1 mo. Results for FIQL not reported. Power not reported. RCT excluded post-randomization data on 21% of sample.	High

*Significant = statistically significant

AE=Adverse Effects; AMS=American Medical System; AM=anal manometry; BDI=Beck Depression Inventory; BM=bowel movement; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; d=day; Est=estimated; Estim=Electrostimulation; F=Female; FI= Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life scale; FU=Followup; FDA=Food and Drug Administration; freq=frequency; GI=gastrointestinal; GSRS-IBS=Gastrointestinal Symptom Rating Scale for Irritable Bowel Syndrome; HAD=Hospital Anxiety and Depression Scale; IAS=internal anal sphincter; IBS=irritable bowel syndrome; mo=month; NR=Not Reported; NSD=No Significant Difference; pt=patient; pd=period; analysis; QoL=Quality of Life; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; surg=surgery; T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; Vaizey=Vaizey Fecal Incontinence Score; VAS=Visual Analogue Scale; wk=week; yr=year

Table F5. KQ 1: Observational studies* of fecal incontinence treatments with study quality ratings

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Results	Risk of Bias (Inverse of Quality)
Nonsurgical							
Sze, 2009[68]	Methyl-cellulose + loperamide vs. no treatment	Prospective	N=69 F: 100% NR FU: 3 mo (T), 8 wk (C)	T: Methylcellulose 1-2 tbsp 2x/d + loperamide 1-2 cap 3x/d (59) C: No treatment (10) 3 mo	FI cure rate: Pescatori, pt-rated improvement, FI urgency, pad use, pt-rated function	Significantly higher cure rate in T vs C (T 46% vs C 0). No attrition.	High
Remes-Troche, 2008[69]	Cholesty-ramine + PFMT-BF vs. PFMT-BF	Prospective	N=42 F: 90% Mixed FU: 3 mo, 1 yr	T: Cholestyramine 2 g/d + PFMT-BF (21) C: PFMT-BF (21) PFMT-BF: 2x/wk; reinforced 3x in 1 yr	Stool frequency/wk, FI episodes/ wk	Significant reduction in FI episodes/wk in both T (-2.2) and C (-1) at 3 mo. No attrition.	Moderate
Byrne, 2005[70]	In-person PFMT-BF vs telephone PFMT-BF	Prospective	N=239 F: 90% Mixed FU: 5 mo	T: In-person PFMT-BF (184) C: Telephone PFMT-BF (55) 1 session/mo for 5 mo	SMFIS, Pescatori, FI severity, QoL	Both groups improved but changes not significantly different by groups for SMFIS, Pescatori, or QoL. Overall attrition 27% (T 14% vs C 30%).	Moderate
Loening-Baucke, 1990[71]	PFMT-BF + medical (fiber, loperamide, Metamucil, other) vs. medical	Prospective	N=17 F: 100% Mixed FU: 3 mo, 1 yr	T: 1 hr PFMT-BF session 3x over 3 mo + 1x/d at home + medical (8) C: Medical (9) 3 mo	Soiling frequency	Soiling frequency decreased in both groups at 3 mo (T 50% vs. C 56%) and 1 yr (T 25% vs. C 44%). At 1 yr, 13% T vs. 11% C free of soiling. Attrition NR.	High
van der Hagen, 2012[72]	Rectal irrigation vs non-FDA	Prospective	N=150 F: 59% NR FU: 6 mo	T: Bulking injection – non-FDA (75) C: Irrigation after defecation for 6 mo (75)	CCFIS, Vaizey, FIQL, FI d/wk, pad use, KEA	FI completely resolved in 44% of irrigation group. No change in other outcomes. Attrition was 4% (3/75).	High
Surgical							
Hong, 2014[73]	Best option for failed AS repair: RS vs. ABS vs. SNS	Retrospective	N= 59 F: 97% Mixed FU: mean= RS 50 mo (4-138); ABS	T_1: RS (33) T_2: ABS (11) T_3: SNS (15)	CCFIS, FIQL	All groups improved; CCFIS change NSD between groups. CCFIS decrease within groups was RS (-6.0), ABS (-10.1), SNS (-8.5). Between group change in FIQL NSD. Followup differed by group.	High

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Results	Risk of Bias (Inverse of Quality)
			36 mo (5-98); SNS 38 mo (3-113))				
Wong, 2012[74]	SNS vs. non-FDA	Retrospective	N=28 F: 100% Mixed FU: SNS 22 mo (10-28 mo)	T_1: MAS – non-FDA (12) T_2: SNS (16) 12 mo SNS device surveillance	CCFIS, FIQL, deferring time (minutes), urgency	SNS group improved significantly in CCFIS (-3.5) and FIQL (scores NR).	High
Wong, 2011[75]	ABS vs. non-FDA	Retrospective	N=20 F: 100% Mixed FU: ABS 23 mo (6-72)	T1: MAS - nonFDA (10)- T2: ABS (10)	CCFIS, FIQL	ABS group significantly improved in median CCFIS (-11.5) and FIQL (scores NR).	High
Ratto, 2010[76]	SNS vs. ASR	Retrospective	N=24 F: 100% Mixed FU: 4 mo, 8 mo, 12 mo; median= SNS 33 mo (6-84); ASR 60 mo (6-96)	T_1: sphincteroplasty (14) T_2: SNS (10)	CCFIS, FI episodes/wk	CCFIS scores improved within both T_1 (-8.7) and T_2 (-8.6). NSD between groups.	High
Dudding, 2009[77]	SNS: open vs. per-cutaneous lead placement	Retrospective	N=48 F: 94% NR FU: 51 mo median (22-106 mo)	T_1: open lead (18) T_2: percutaneous lead (30)	Urgency, FI episodes/wk, soiling/wk	Urgency significantly reduced in both T_1 (-1.5) and T_2 (-2). NSD between groups. No change in FI episodes or soiling.	High
Steele, 2006[78]	Sphincteroplasty +/- PFR	Retrospective	N=28 F: 100% Mixed FU: 34 mo (mean)	T: Sphincteroplasty + PFR (17) C: Sphincteroplasty (11)	CCFIS, pt-rated satisfaction	CCFIS significantly worse in T vs C overall (T 14.2 vs C 5.1). NSD between groups. NSD between groups for pt-rated satisfaction.	High
Tan, 2001[79]	ASR: compare incision placement	Retrospective	N=50 F: 100% Obstetric FU: 23 mo (mean)	T_1: Posterior fourchette incision (18) T_2: perineal incision (32)	Modified Pescatori	Modified Pescatori significantly improved in both T_1 (-8.4) and T_2 (-7.4).	Moderate

Author, Year	Study Aim	Prospective or Retrospective	N analyzed; % Female; FI etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Results	Risk of Bias (Inverse of Quality)
Osterberg, 2000[80]	Anterior levatorplasty vs. sphincteroplasty	Prospective	N=51 F: 100% Idiopathic FU: 3 mo, 1 yr	T_1: AL (31) T_2: sphincteroplasty (20)	Miller, social and physical handicap	Significant improvements in Miller for both T_1 (-11) and T_2 (-5) at 1 yr. Attrition NR.	High
Briel, 1998[81]	ASR: compare surgical approach	Retrospective	N=55 F: 100% Obstetric FU: 2 yr	T_1: direct ASR (24) T_2: anterior ASR (31)	Continence restored (Grade IV to I/II or Grade III to I via Parks)	Continence restored in 63% (15/24) T_1 and 68% (21/31) T_2.	High

*With comparator/control group

+=with; +/-=with and without; ABS=artificial bowel sphincter; AL=anterior levatorplasty; AS=anal sphincter; ASR=anal sphincter repair; BF=biofeedback; C=comparator; cap=capsules; CCFIS=Cleveland Clinic Fecal Incontinence Scale; d=day; EAS=external anal sphincter; F=female; FDA=Food and Drug Administration; FI=fecal incontinence; FIQL=Fecal Incontinence Quality of Life Scale; FU=followup; g=grams; hr=hour; KEA=KEA quality of life questionnaire score; MAS=magnetic anal sphincter; Miller= Miller's Incontinence Score; N=total patients in study; n=patients in study arm; NR=not reported; NSD=No significant difference; Parks=Browning and Parks Incontinence Score; Pescatori=Pescatori Fecal Incontinence Score; PFMT=pelvic floor muscle training; PFR=pelvic floor repair; pt=patient; QoL=quality of life; RS=repeat sphincteroplasty; SD=standard deviation; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SMFIS=St. Mark's Fecal Incontinence Score; SNS=sacral nerve stimulation; UTI=urinary tract infection; T=treatment group; T_1=Treatment group 1; T_2=Treatment group 2; T_3=Treatment group 3; tbsp=tablespoon; Vaizey=Vaizey Fecal Incontinence Score; vs=versus; wk=week; x=repetition; yr=year

Table F6. KQ 2: Adverse effects of nonsurgical treatments for fecal incontinence in randomized controlled trials

Author, Year	Study Aim	N Randomized; n Analyzed; % Female; FI Etiology; Treatment and Followup Duration	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome **bolded** if known)	Reported Harms	Attrition*
Dietary fiber						
Bliss, 2014[54] *Note: Same sample as Bliss 2011*[82]	Compare fiber supplements	N=206 n=206 F: 74% NR T: 38 d FU: 38 d	T_1: carboxymethy-cellulose (CMC) (53) T_2: gum arabic (50) T_3: psyllium (54) C: placebo (49)	**FI frequency**, amount, consistency, severity; FIQL	Overall: NR T_1: 11% T_2: None T_3: 11% C: None GI symptoms and allergic reaction most common.	8%* T_1: 11% T_2: 2% T_3: 15% C: 4%
Bliss, 2001[20]	Compare fiber supplements	N=39 n=39 F: 79% NR T: 31 d FU: 31 d	T_1: psyllium (13) T_2: gum arabic (13) C: placebo (13)	% incontinent, stool frequency, stool consistency, dietary intake	No serious AEs reported.	7%* (3/42 withdrew in baseline, unrelated to treatment)
Lauti, 2008[57]	Does fiber supplement and loperamide improve FI over low residue diet and loperamide	N: 63 n: 47 F: 91% Mixed T: 12 wk (6 + 6) FU: 6 wk, 12 wk	Crossover T: balanced fiber diet + fiber supplement + loperamide (32) C: low residue diet + placebo fiber + loperamide (31)	**FISI**, FIQL	No AEs occurred	25% T: 22% C: 29%
Drugs: Sphincter function enhancers						
Park, 2007[58]	Efficacy of 30% phenylephrine gel for FI after low anterior resection for rectal cancer	N=35 n=29 F: 37% Postsurgical T: 4 wk FU: 4 wk	T: 30% topical phenylephrine (17) 2x/day C: placebo 2x/d (12)	FISI, FIQL, Global Efficacy	Overall: 35% nonserious AEs T: 41% nonserious AEs; local allergic dermatitis 29%, headache 12% C: 17% nonserious AEs	Excluded post-randomization data from 17% with poor compliance
Carapeti, 2000[64]	Effectiveness of 10% topical phenylephrine in FI patients with IAS dysfunction	N=36 n=36 F: 61% NR T: 4 wk each FU: 4 wk, 8 wk	Crossover, 1 wk washout T: topical 10% phenylephrine gel (anus) 2x/d (36) C: placebo gel (36)	**Vaizey score**, subjective improvement	Overall: No serious AEs T: 8% nonserious AEs; mild dermatitis (erythema & pruritus) most common C: None	Not reported

Drugs: Antidiarrheals						
Sun, 1997[27]	Effectiveness of loperamide oxide for chronic diarrhea with FI	N=11 n=11 F: 73% Mixed T: 1 wk each FU: 2 wk 4 wk	Crossover, 1wk run-in, washout T: loperamide 8mg/d (11) C: placebo(11)	FI episodes, % fully continent, stool freq/consistency, urgency, FI severity, diarrhea, abdominal pain	Overall: NR T: 55% nonserious AEs C: 27% nonserious AEs Abdominal pain, headache & nausea most common	None
Hallgren, 1994[14]	Effectiveness of loperamide HCl after proctoco-lectomy for ulcerative colitis	N=30 n=28 F: 27% Postsurgical T: 8 d each FU: 15 d, 30 d	Crossover, 1wk run-in, washout T: loperamide HCl 12mg/d (30) C: placebo (30)	Defecation freq, need for night evacuation, FI episodes, use of pads, flatus release	No AEs occurred	7%*
Read, 1982[30]	Effectiveness of loperamide for chronic diarrhea with FI and urgency	N=26 n=26 F; 57% Mixed T: 1 wk each FU: 1 wk, 2 wk	Crossover, washout NR T: loperamide 12mg/d (26) C: placebo (26)	FI episodes; stool freq, weight and consistency; urgency; improvement in FI and urgency	Overall: No serious AEs reported. T: 69% nonserious AEs C: 4% nonserious AEs Constipation, exacerbation of diarrhea, abdominal pain, and nausea & vomiting most common	None
Palmer, 1980[22]	Compare 3 drugs for chronic diarrhea (95% had urgency with FI)	N=30 n=25 F: NR Mixed T: 4 wk each FU: outcomes every 4 wk up to 12 wk	Crossover; used 3 wk data per period T_1: loperamide HCl 2mg/d (30) T_2: codeine phos-phate 45mg/d (30) T_3: diphenoxylate 5mg/d (30)	FI episodes, # of patients with FI, stool freq. and consistency, urgency episodes, dose/capsule consumption	Overall: NR T_1: 22 AEs in 40% of group T_2: 29 AEs in 48% of group T_3: 39 AEs in 48% of group Abdominal pain, vomiting, constipation most common AEs causing withdrawal.	17% AEs caused discontinuation of treatment: T_1: 16%* T_2: 16%* T_3: 20%* Abdominal pain, vomiting, constipation most common in withdrawals. 5 withdrew due to idiopathic diarrhea
Drugs: Other						
Bharucha, 2014[53]	Effectiveness of clonidine vs. placebo in women with FI	N=44 n=44 F: 100% Mixed T: 4 wk FU: 4 wk	T: Clonidine 0.2mg/d (22) C: placebo (22)	**FICA**, FI count, days of FI, FIQL, FISI, satisfaction, rectal urgency, loperamide use	Overall: No serious AEs. T: 86% nonserious AEs C: 32% nonserious AEs Dry mouth, fatigue, light-headedness and drowsiness most common.	4%* T: 4% C: None

Pinedo, 2012[39]	Compare Zn-Al ointment to anal submucosa vs. placebo for FI	N=50 n=44 F: NR NR T: 1 mo FU: 1 mo	T: Zinc-aluminum ointment 3x/d (25) C:placebo(25)	**CCFIS**, FIQL	No AEs occurred	12% * T: 4% C: 20%
Pinedo, 2009[42]	Compare topical estrogen vs. placebo for FI in postmenopausal women	N=36 n=35 F: 100% NR T: 3x/d for 6 wk FU: 6 wk	T: Estrogen cream to anal submucosa (18) C: placebo(18)	**CCFIS,** FIQL	Overall: NR T: 28% nonserious AEs; mild pruritus ani C: None	3%* T: None C: 6%
Kusunoki, 1990[25]	Effectiveness of valproate sodium for FI after ileoanal anastomosis	N=17 n=17 F: 24% Postsurgical T: 1 wk FU: 1 wk	Crossover, 3 d washout T: Valproate sodium 1600mg/d (17) C: placebo (17)	FI count (soiling), stool freq, perianal skin trouble	Overall: No serious AEs reported. T: 47% nonserious AEs; nausea and abdominal pain most common. C: None	None
PFMT with biofeedback (BF)						
PFMT-BF vs. standard care						
Damon, 2014[37]	Does PFMT-BF plus standard care improve FI outcomes over standard care only?	N=157 n=92-142 (varied per analysis) F: 77% Mixed T: 4 mo FU: 4 mo	T: PFMT-BF (20 sessions) plus standard care (77) C: standard care of laxative, oral bulking agent, loperamide (80)	**Treatment effectiveness** (-5 to 5), CCFIS, FIQL, KESS, SF-12, symptom change	No AEs occurred	10%* T: 13% C: 6%
PFMT-BF vs. PFMT with digital rectal feedback (DRF)						
Bols, 2012[66]	Does PFMT-BF with rectal balloon improve FI over PFMT (digital rectal feedback)?	N=80 n=80 (ITT) F: 90% Mixed T: 9 wk FU: 4.5 mo (varied)	12 sessions/9 wk: T: PFMT-BF plus rectal balloon (40) C: PFMT "alone" (with DRF) (40)	**Vaizey** (0-24); FIQL, GPE	No AEs occurred	13% T: 8% C: 18%
Compare exercises						
Bartlett, 2011[26] *rectal balloon*: both	Compare exercises: PFMT-BF (RBT) mixed exercise vs. PFMT-BF (RBT) sustained contraction	N=72 n=69 (2 mo); 53 at 2 yr F: 74% Mixed T: 5 sessions/2 mo FU: 2 mo, 2 yr	5 sessions/8 wk: T: PFMT-BF rapid & sustained contraction (35) C: PFMT-BF, sustained contraction (37)	**CCFIS**, FIQL, self-rated improvement	No AEs occurred	2 mo: 4%* T: 3% C: 5% 2 yr: 26%* T; 29% C: 24%
PFMT-BF with electrostimulation (estim): Compare frequencies						
Schwandner, 2011[19]	Does PFMT-BF	N=80	T: Estim (medium	**CCFIS**, adapted	Overall: NR	3 mo: 9%*

	with medium freq estim improve FI over PFMT-BF with low freq estim)?	n=80 (ITT) F: 81% Mixed T: 6 mo FU: 3 mo, 6 mo	freq) with PFMT-BF (39) C: Estim (low freq.) with PFMT-BF (41)	Vaizey (0-24), FIQL, ICIQ-SF, % complete responders	T: None C: 50%; pain during estim most common	T: 5% C: 12% 6 mo: 11%* T: 8% C: 15%
Electrostimulation						
Norton, 2006[63]	Does home-based estim without PFMT improve FI over sham home-based estim?	N=90 n=90 (ITT) F: 90% Idiopathic T: 2 mo FU: 2 mo	T: estim 35Hz 20 min/d x 3 wk, then 40 min/d x 5 wk (47) C: same protocol but 1Hz estim (43)	Symptom change outcome rating, FI counts/w, 0-10 of bowel control & satisfaction, effectiveness	Overall: Discomfort 9%	22% T: 21% C: 23%
Rectal irrigation						
Christensen, 2006[18]	Compare transanal irrigation to best supportive care	N=87 n=79-87 (ITT) F: 29% Spinal cord injury T: 10 wk FU: 10 wk	T: Transanal irrigation 1x/d then every 2 d or less (42) C: bowel care every 2 d, diet, physical activity, laxatives or constipating drugs (45)	**CCCS**, **Vaizey** ("SMFIS"), modified FIQL, neurogenic bowel dysfunction score; satisfaction, bowel function, daily activities	Overall: NR T: Bursts of rectal balloon during irrigation (24%*; reported as occurring in 1 in every 3 patients); abdominal distention (2%), hospitalization for severe abdominal pain from constipation (5%), other AE NR (2%). C: None	14%* T: 25% C: 4% Withdrawals for repeated expulsion of rectal catheter during irrigation (7%); bursts of rectal balloon (2%)
Mixed nonsurgical						
Coggrave, 2010[52]	Does stepwise intervention improve bowel management & reduce FI over usual care?	N: 68 n: 68 (ITT) F: 34% Spinal cord injury T: 6 wk FU: 6 wk	T: Stepwise intervention (7 steps, least to most invasive) (35) C: Usual bowel management (33)	**Duration and level of intervention required**, FI frequency, time to stool, minimum level of effective intervention	Overall: No serious AEs T: 1% nonserious AE C: None	26%* T: 40% C: 12%
Percutaneous tibial nerve stimulation (PTNS)						
Thin, 2015[36]	Compare PTNS with SNS	N=40 n=31 98% F; 59 y Mixed T: 5 mo (PTNS) FU: 3 mo., 6 mo.	T: PTNS 15 sessions: 12 in 3 mo, plus 3 over 2 mo. (16) C: SNS (15)	FI episodes, CCFIS, SF-36, EQ-5D; qualitative interview	No serious AEs occurred Nonserious: T: transient paresthesias (6%) or pain (6%). C: 20%: leg pain or site pain (resolved)	None
Local tissue-bulking injections						
Dehli, 2013[65]	Determine if tissue bulking injections with dextranomer superior to	N: 126 n: 119 (6 mo) F: 93% Mixed T: 6mo control	T: Dextranomer in hyaluronic acid (4 x 1ml injections to anal submucosa); repeat 1x if needed	**Vaizey** ("St. Mark's" 0-24), FIQL, EQ-5D	Overall: NR T: 25%; leakage of injected agent, infection, prolonged defecation most common C: 8%; pain using anal	3%* T: None C: 5% Withdrew consent after

	PFMT with biofeedback (plus estim if needed) for FI	FU: 6 mo (RCT to 6 mo; observed successes to 2 yr)	(64) C: PFMT-BF plus estim if needed x 6 sessions/6 mo (62)		probe most common.	randomization: T: n=2 C: n=4
Graf, 2011[40]	Does anal canal injection of dextranomer in stabilized hyaluronic acid improve FI over sham?	N=206 n=197 (6 mo); 125 (1 yr treated only) F: 89% Mixed T: Injections (1 d); repeat in 1 mo if CCFIS >10 FU: 3 mo, 6 mo; 1 yr for treated group	T: Total of 4-8 ml dextranomer injections in four quadrants of anal submucosa (136) C: Sham injections (no substance injected) (70)	**FI counts/wk (50% or more reduction from baseline**) CCFIS, FIQL, number of FI-free days, decrease in FI episodes	Overall: NR Serious AEs: T: rectal abscess (1%), prostate abscess (1%) C: None Nonserious AEs: T: proctalgia (14%), rectal hemorrhage (7%), diarrhea (5%), constipation (2%), injection site bleeding (5%), rectal discharge (4%), anal pruritus (2%), proctitis (3%), painful defecation (2%), fever (8%), other (16%) C: proctalgia (3%), rectal hemorrhage (1%), diarrhea (4%), injection site bleeding (17%), others (7%)	6 mo: 4% T: 3% C: 7% By 1 yr: T: 8% C: Not followed beyond 6 mo.
Off-label & only 1 arm FDA approved						
Morris, 2013[38] injected outpatient surgery	Compare injectable bulking agents: Durasphere® (off-label) vs PTQ™ (not FDA approved)	N=35 n=34 overall F: NR NR T: 1 d FU: 6 wk, 6 mo, 1 yr	T_1: Durasphere®: perianal injection (18) T_2: PTQ™ (not-FDA approved) (17)	**CCFIS**, SF-36	Overall: NR T_1: None T_2: NR	6%
Tjandra, 2009[43]	Compare injectable bulking agents: Durasphere® (off-label) vs. PTQ™ (not FDA approved)	N=40 n=40 overall F: 90% Mixed T: 1 d FU: 2 wk, 6 wk, 6 mo, 1 yr	T_1: Durasphere®: perianal injection (20) T_2: PTQ™ (not-FDA approved) (20)	**CCFIS**, FIQL, SF-12	Overall: NR T_1: Serious AEs: rectal pain (5%), erosion through rectal mucosa (10%), hypersensitivity reaction (required hospitalization & IV steroids, 5%). Nonserious AEs: bruising (20%). T_2: NR	None

*Attrition based on the number randomized. Attrition (n, %) was calculated by the MN EPC when study authors reported attrition only among the subset of patients who completed the study or perfectly completed the protocol.

AE=Adverse Effects; AMS=American Medical System; AM=anal manometry; BDI=Beck Depression Inventory; BM=bowel movement; CCCS= Cleveland Clinic Constipation Score; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control ; d=day; dx=diagnosis; DRF: digital rectal feedback; DYS=Dysfunctional; E-diary=Electronic

diary; EQ-5D=EuroQoL Questionnaire-5 Dimensions; F=Female; FI=Fecal incontinence; FICA=Fecal Incontinence and Continence Assessment; FIQL=Fecal Incontinence Quality of Life scale; FISI=Fecal Incontinence Severity Index; FU=Followup; FDA=Food and Drug Administration; freq=frequency; GI=gastrointestinal; g=Grams; HAD: Hospital Anxiety and Depression Scale; IAS=internal anal sphincter; IBS=irritable bowel syndrome; ITT=Intention-to-treat analysis; M=Male; mo=month; mg=milligrams; ms=microseconds; neurogenic bowel dysfunction score (NBDS); NR=Not Reported; NSD=No Significant Difference; pt=patient; PFMT=Pelvic floor muscle training; pd=period; PP=Per protocol analysis; PTQ™=injectable bulking agent not FDA approved for use in the US; QoL=Quality of Life; reps: repetitions; SMFIS=St. Mark's Fecal Incontinence Score; s=Seconds; SAE=Serious Adverse Event; SF-12=Short-Form-12 health survey; SF-36=Medical Outcomes Study Short-Form 36-item Health Survey; surg=surgery; T_1=Treatment group 1 T_2=Treatment group 2 T_3=Treatment group 3; TEAE=Treatment Emergent Adverse Event; Vaizey=Vaizey Fecal Incontinence Score; VAS=Visual Analogue Scale; wk=week; y=year

Table F7. KQ 2: Adverse effects of treatments for fecal incontinence in observational studies with comparison groups

Author, Year	Study Aim	Prospective or Retrospective	N Analyzed; % Female; FI Etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Harms	Attrition
Nonsurgical							
Sze, 2009[68]	Methyl-cellulose + loperamide vs. no treatment	Prospective	N=69 F: 100% NR FU: 3 mo (T), 8 wk (C)	T: Methylcellulose 1-2 tbsp 2x/d + loperamide 1-2 cap 3x/d (59) C: No treatment (10) 3 mo	FI cure rate: Pescatori, pt-rated improvement, FI urgency, pad use, pt-rated function	Overall: 5% (3/59) T: constipation and abdominal cramps	None
Remes-Troche, 2008[69]	Cholesty-ramine + PFMT-BF vs. PFMT-BF	Prospective	N=42 F: 90% Mixed FU: 3 mo, 1 yr	T: Cholestyramine 2 g/d + PFMT-BF (21) C: PFMT-BF (21) PFMT-BF: 2x/wk; reinforced 3x in 1 yr	Stool frequency/wk, FI episodes/ wk	Overall: 33% Constipation, excessive gas, abdominal bloating, headache most common	None
van der Hagen, 2012[72]	Rectal irrigation vs non-FDA	Prospective	N=150 F: 59% NR FU: 6 mo	T: Bulking injection – non-FDA (75) C: Irrigation for 6 mo (75)	CCFIS, Vaizey, FIQL, FI d/wk, pad use, KEA	None occurred with irrigation	4% (3/75)
Surgical							
Hong, 2014[73]	Best option for failed AS repair: RS vs. ABS vs. SNS	Retrospective	N= 59 F: 97% Mixed FU: mean= RS 50 mo (4-138); ABS 36 mo (5-98); SNS 38 mo (3-113	T_1: RS (33) T_2: ABS (11) T_3: SNS (15)	CCFIS, FIQL	Overall: 36%; wound infection most common: ABS: 73% , RS: 24% SNS: 33%; Reoperation for device removal: ABS: 55%, SNS: 40%	NA
Wong, 2012[74]	SNS vs. non-FDA	Retrospective	N=28 F: 100% Mixed FU: median= MAS 18 mo (8-30); SNS 22 mo (10-28)	T_1: MAS – non-FDA (12) T_2: SNS (16)	CCFIS, FIQL, deferring time (minutes), urgency	2 AEs: 1 patient (6%) had device removed for infection 1 yr after implantation; 1 patient had occasional constipation.	NA
Wong, 2011[75]	ABS vs. non-FDA	Retrospective	N=20 F: 100% Mixed FU: median=	T1: MAS – non-FDA (10) T2: ABS (10)	CCFIS, FIQL	Serious AEs in 40% (4/10): 4 needed revisions (3 leakage from anal cuff, 1 pressure-regulating balloon); of these 1 infection, 1	NA

Author, Year	Study Aim	Prospective or Retrospective	N Analyzed; % Female; FI Etiology; Followup Duration	Study Groups (n) Treatment Duration	Patient-Reported Outcomes	Reported Harms	Attrition
			MAS 8 mo (6-13); ABS 23 mo (6-72)			severe pain.	
Dudding, 2009[77]	SNS	Retrospective	N=48 F: 94% NR FU: 51 mo median (22-106 mo)	T_1: open lead (18) T_2: percutaneous lead (30)	Urgency, FI episodes/wk, soiling/wk	Serious AEs in 6% (3/48): T_1: 2 wound infections T_2: 1 lead dislocation requiring surgery	NA
Steele, 2006[78]	Sphincteroplasty +/- PFR	Retrospective	N=28 F: 100% Mixed FU: 34 mo (mean)	T: Sphincteroplasty + PFR (17) C: Sphincteroplasty (11)	CCFIS, pt-rated satisfaction	Overall: 43% serious AEs; 39% required further surgery. T: 47%: wound separation (7), infection (2), abscess (1), stenosis (2), impaction (1), and urinary retention (3) C: 36%: wound separation (5), infection (1), abscess (1)	NA
Tan, 2001[79]	ASR: compare incision placement	Retrospective	N=50 F: 100% Obstetric FU: 23 mo (mean)	T_1: Posterior fourchette incision (18) T_2: perineal incision (32)	Modified Pescatori	Wound complications: T_1 11%, T_2 44% ; Wound breakdown: T_1 6%, T_2 16%	NA
Osterberg, 2000[80]	Anterior levatorplastyvs. sphincteroplasty	Prospective	N=51 F: 100% Idiopathic FU: 3 mo, 1 yr	T_1: AL (31) T_2: sphincteroplasty (20)	Miller, social and physical handicap	Serious AEs in 6% T_1 (2 wound infections)	NR
Briel, 1998[81]	ASR	Retrospective	N=55 F: 100% Obstetric FU: 2 yr	T_1: direct ASR (24) T_2: anterior ASR (31)	Continence restored (via Parks)	11 AEs reported: Wound abscess (T_1 3 vs T_2 2); UTI (T_1 2 vs T_2 0) T_2 other: 1 perineovaginal fistula, 1 rectovaginal fistula, 1 dyspareunia/breakdown	NA

+=with; +/-=with and without; ABS=artificial bowel sphincter; AE=adverse effect; AL=anterior levatorplasty; AS=anal sphincter; ASR=anal sphincter repair (sphincteroplasty); BF=biofeedback; C=comparator; cap=capsules; CCFIS=Cleveland Clinic Fecal Incontinence Scale; d=day; EAS=external anal sphincter; F=female; FDA=Food and Drug Administration; FI=fecal incontinence; FIQL=Fecal Incontinence Quality of Life Scale; FU=followup; g=grams; hr=hour; KEA=KEA quality of life questionnaire score; KQ 2=Key Question 2; MAS=magnetic anal sphincter; Miller= Miller's Incontinence Score; N=total patients in study; n=patients in study arm; NA=not applicable; NR=not reported; NSD=No significant difference; Parks=Browning and Parks Incontinence Score; Pescatori=Pescatori Fecal Incontinence Score; PFMT=pelvic floor muscle training; PFR=pelvic floor repair; pt=patient; QoL=quality of life; RS=repeat sphincteroplasty; SD=standard deviation; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SMFIS=St. Mark's Fecal Incontinence Score; SNS=sacral nerve stimulation; UTI=urinary tract infection; T=treatment group; T_1=Treatment group 1; T_2=Treatment group 2; T_3=Treatment group 3; tbsp=tablespoon; Vaizey=Vaizey Fecal Incontinence Score; vs=versus; wk=week; x=repetition; yr=year

Table F8. KQ 2: Adverse effects of surgical treatments for fecal incontinence in randomized controlled trials

Author, Year	Study Aim	N Randomized; n Analyzed; % Female; FI Etiology; Treatment and Followup	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded)	Reported Harms	Attrition*
Surgical Treatments						
Anal sphincter repair						
Hasegawa, 2000[50]	Is anal sphincter repair with fecal diversion superior to sphincter repair?	N=27 n=27 F: 96% Mixed T: surgery FU: mean 34 mo	**T**: Anal sphincter repair + stoma (fecal diversion) (13) **C**: Anal sphincter repair (14)	**CCFIS**	Overall: No nonserious AEs reported. T: 12 serious AEs in 13 patients; wound infection, parastomal hernia, prolapsed stoma, incisional hernia at stoma site. C: 3 serious AEs in 14 patients; wound infection, fistula, fecal impaction. Trial stopped after 3 yrs due to high rate of complications and no treatment advantage in anal sphincter repair + stoma group.	None
Anal sphincter replacement						
O'Brien, 2004[49]	Effectiveness of artificial bowel sphincter (ABS) vs. conservative management for severe FI	N=14 n=13 F: 93% Mixed T: surgery FU: 3 mo, 6 mo	**T**: Artificial Bowel Sphincter (Action Neo-sphincter®) (7) **C**: Conservative medical management (7)	**CCFIS**, SF-36, AMS QoL scale, BDI	Overall: No nonserious AEs reported. Serious AEs: T: 43%; failure of perineal wound healing that required explant and colostomy (14%), prolonged hospital stay, inability to evacuate without assistance, delayed healing of perineal wound that required resuturing C: None	7%* T: 14% C: None
Other surgeries						
Yoshioka, 1999[21]	Total pelvic floor repair (TPFR) vs. gluteus maximus transposition (without electrical stimulation) for post-obstetric neuropathic FI	N=24 n=24 F: 100% Obstetric: intact sphincter T: surgery FU: 18 mo	**T_1**: Total pelvic floor repair (TPFR) (12) **T_2**: GMT without estim (12)	CCFIS, FI improvement bowel habit, rectal evacuation, urgency, soiling	Overall: No nonserious AEs reported. T_1: 8% serious AEs T_2: 25% serious AEs Wound sepsis, wound hematoma, fecal impaction most common.	None
Deen, 1993[51]	Compare total pelvic floor repair (TPFR) vs. anterior levatorplasy vs. postanal repair for neurogenic FI	N=36 n=20 F: 100% Neurogenic T: surgery FU: 6 mo, 2 yr	**T_1**: TPFR (12) **T_2**: Anterior levatorplasty (12) **T_3**: Postanal repair (12)	Complete continence, FI freq, extent of FI (0-10)	AEs during surgery not reported. Serious AEs NR by group: Wound infection (1), iatrogenic incision of anterior wall of anorectum (1). More nonserious AEs with TPFR & anterior levatorplasty vs. postanal repair (42%	None

Author, Year	Study Aim	N Randomized; n Analyzed; % Female; FI Etiology; Treatment and Followup	Study Groups (n per group)	Patient-Reported Outcomes (primary outcome bolded)	Reported Harms	Attrition*
					dyspareunia, 42% dyspareunia vs 0);	
Surgical vs nonsurgical						
Osterberg, 2004[29]	Compare levatorplasty vs. anal plug electro-stimulation for neurogenic FI	N=70 n=59 F: 88% Neurogenic T: surgery vs 4 wks (median) FU: 3 mo, 1 yr, 2 yrs	**T_1**: Anterior levatorplasty (31) **T_2**: Anal plug electrostimulation (28)	MISS, stool freq, pad use, physical & social handicap, deferring time	Overall: NR Serious AEs: T: 3%; wound infection C: None Nonserious AEs: T: None C: 9%; pain, burning sensation in vagina most common.	16%* T: 11% C: 20%
Sacral neurostimulation (SNS)						
Tjandra, 2008[44]	Is SNS better than best supportive care for FI?	N=120 n=113 (7 failed SNS pre-test) F: 93% (est.) Mixed T: 1 d up to 1 yr FU: 3 mo, 6 mo, 1 yr	**T**: SNS (53) **C**: Supportive care=diet, oral bulking agents, PFMT; met with pelvic floor team 12-18x/1 yr.(60)	CCFIS, bowel diary, FIQL, SF-12	Overall: No serious AEs reported. T: pain at implant site (6%); seroma (2%); vaginal tingling (9%) C: constipation from Immodium (10%)	None
Leroi, 2005[28]	Effectiveness of SNS with stimulation ON vs OFF for FI in new SNS recipients	34 pts received SNS but N=27 randomized; n=24 F: 91% Mixed T: 1 mo x 2 FU: 2 mo: 1 mo x 2	Crossover, no washout **T_1**: Stimulation ON (27) **T_2**: Stimulation OFF (27)	FI count, CCFIS, FIQL, urgency episodes, postponing defecation, bowel movements	NR during trial period. Prior to randomization during implantation period, 4 patients withdrew due to unresolved pain (3) and recurrent infection (1).	10%*

* Attrition calculated by the MN EPC based on the number randomized

ABS=artificial bowel sphincter; AE=adverse effects; AMS=American Medical Systems; BDI=Beck Depression Inventory; C=Comparator ; d=day; CCFIS=Cleveland Clinic Florida Fecal Incontinence Score; est.=estimated; estim=intra-anal electrostimulation; F=Female; FI=Fecal Incontinence; FIQL=Fecal Incontinence Quality of Life Instrument; freq=frequency; FU=followup; GMT=gluteus maximus transposition; IAS=internal anal sphincter; IBS=irritable bowel syndrome; ICIQ-BS=International Consultation Incontinence Questionnaire Bowel Symptoms; MISS=Miller's Incontinence Score System; mo=month; NA=not applicable; NR=not reported; PFMT=pelvic floor muscle training; PP=per protocol analysis; pt=patient; QoL=Quality of Life; SECCA=Radiofrequency anal sphincter remodeling; SF-12=MOS Short-Form 12-item Health Survey; SF-36=MOS Short-Form 36-item Health Survey; SNS=sacral nerve stimulation; T1=Treatment group 1; T2=Treatment group 2; T3=Treatment group 3; TPFR=total pelvic floor repair; wk=week; x=times; yr=year

Table F9. KQ 2: Adverse effects reported in surgical case series of fecal incontinence treatments

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
SECCA			
Abbas, 2012[83]	Safety and long-term efficacy of temperature-controlled radiofrequency energy (the SECCA® procedure) for FI at a single institution	N: 27 (31 procedures) 81% 64 yr Mixed 6 mo (3-40)	Serious: None Other: Minor complications in 5 pts (19%), including anal bleeding (15%) and swelling of the vulva (4%).
Ruiz, 2010[84]	Efficacy of the SECCA® procedure at 1 yr followup	N: 24 96% 73 yr (in 16 pts) Mixed 1 yr	Serious: Surgical complication in 3 pts (13%); including postoperative bleeding and diarrhea. Other: Minor complication in 5 pts (21%); including side effects from preparation for procedure in 4 pts (nausea/vomiting, allergic reaction, abscess formation, urinary tract infection), constipation following surgery (1 pt.)
Takahashi-Monroy, 2008[85]	Long-term (5 yr) efficacy and safety of the SECCA® procedure	N: 19 95% 57 yr Mixed 5 yr	Serious: Surgical complications in 6 pts (32%), including delayed bleeding (with 1 pt requiring anoscopy and suture ligation). Other: Authors report no long-term complications observed.
Lefebure, 2008[86]	Efficacy of the SECCA® procedure at a single institution at 1 yr followup	N: 15 93% 53 yr Mixed 1 yr	Serious: None Other: Authors report no immediate surgical or long-term complications observed.
Felt-Bersma, 2007[87]	Efficacy and safety of the SECCA® procedure	N: 11 100% 61 yr Mixed 1 yr	Serious: Authors report no major side effects. 3 pts (27%) experienced pain during procedure. Other: Minor adverse effects occurred in 16 patients; pain, hematoma and/or minor bleeding, and antibiotic-associated diarrhea most common.
Efron, 2003[88]	Efficacy and safety of the SECCA® procedure	N: 50 86% 61 yr Mixed 6 mo	Serious: Surgical complication in 3 pts (6%); including mucosal ulceration (1 superficial, 1 with underlying muscle injury) and delayed bleeding from hemorrhoidal vein required suture ligation. Delayed surgical complication in 1 pt (2%) at 3 mo; stercoral perforation required a colostomy. Other: Mild bleeding during procedure not requiring intervention occurred in 11 pts (22%); 26 minor AE following procedure; antibiotic-associated diarrhea, minor bleeding, pain, and fever not associated with infection most common.

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
ACE/MACE			
Chereau, 2011[89]	Long-term efficacy of the antegrace colonic enema (ACE) procedure among adults	N: 75 72% 48 yr* Mixed 4 yr (median) (4-110 mo)	Serious: Early surgical complications (<3 mo.) in 4 pts (5%); wound infection and hematoma most common. Late surgical complications (>3 mo.) requiring re-admission in 12 pts (16%); stenosis of stoma, large bowel obstruction, stoma prolapse most common. Recurrent impaction in half of pts who had prior impaction. Other: Minor adverse effects occurred in 11 pts (15%); reflux from stoma, pain most common.
Worsoe, 2008[90]	Long-term efficacy of the ACE alone and ACE combined with colostomy, among adults with FI and/or constipation	N: 80 80% 51 yr Mixed 6.25 yr (mean) (3-183 mo)	Serious: Early surgical complications (<3 mo.) in 19 pts (24%); wound infection, infection, urinary tract infection most common. Late surgical complications (>3 mo.) in 11 pts (15%); stenosis of appendicostomy, perforation most common. Other: Minor adverse effects in 27 pts (63%); autonomous symptoms (chills, nausea), painful catheterization, skin problems or rectal bleeding most common.
Koivusalo, 2008[91]	Efficacy of the ACE procedure for congenital FI in adults	N: 27 66% 19 yr* Mixed 25 mo (median) (3-117 mo)	Overall: Unclear adverse effects reporting. Serious: Perioperative complications (<1 mo.) in 3 pts (11%); iatrogenic small bowel perforation, posteroperative ileus, pelvic abscess most common. Late surgical complications in 17 pts (63%); peristomal infection, conduit stenosis (at skin level, fascial level), excessive fecal reflux, excess mucosal tissue most common. Re-operation for late complications in 13 pts (48%), totaling 25 additional procedures. Other: Minor adverse events not reported.
Krogh, 1998[92]	Efficacy of the ACE procedure in adults with FI and/or constipation	N: 16 (10 pts with FI) 63% 41 yr Mixed 17 mo (1-39 mo)	Serious: Surgical complications reported in 7 pts (44%); wound infection, stenosis of the appendicostomy most common. In 1 pt with stenosis of stoma, revision required. Other: Minor adverse events in 4 pts (25%); abdominal pain most common.
Sphincter repair			
Oom, 2009[93]	Efficacy of anterior sphincteroplasty (overlapping sphincteroplasty)	N: 172 97% 57 yr Mixed 111 mo (12-207 mo)	Serious: Postoperative complication in 39 pts (23%); wound infection most common, with 21 pts (12%) requiring reoperation. Other complications ileus, deep vein thrombosis, and pulmonary embolism. Other: Minor adverse effects not reported.
Kaiser, 2008[94]	Efficacy of anterior sphincteroplasty among women with cloaca-like deformity from obstetric trauma	N: 12 100% 37 yrs* OB 39 mo (mean)	Serious: Postoperative complication in 3 pts (25%); rectovaginal fistula most common. In 1 pt, faecal diversion and bulbocavernosus flap required. Other: Minor infections reported in 8 pts (67%).

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
Grey, 2007[95]	Report short and long term outcomes from anterior sphincter repair; identify factors in long term success	N: 85 82% 46 yr Structural 12 yr (mean) (5-12 yr range)	Serious: Surgical complications in 23 pts (27%); wound infection, urinary tract infection, hematoma, fecal impaction, pain most common. Other: Minor adverse effects not reported.
Ha, 2001[96]	Efficacy of overlapping anal sphincter reconstruction	N: 49 (52 procedures) 94% 44 yr Mixed 6 mo	Serious: 13 pts (27%) experienced 15 surgical complications; wound complication, fecal impaction, rectovaginal fistula most common. Other: Minor adverse effects not reported.
Ho, 1999[97]	Efficacy of anterior anal sphincter repair	N: 15 100% 51 yr OB 42 mo (mean)	Serious: Surgical complications in 4 pts (26%); wound infection and two stitch sinuses most common. Repeat anterior sphincter repair in 1 pt (7%). Other: Minor adverse effects not reported.
Sitzler, 1996[98]	Efficacy of anal sphincter repair	N: 31 87% 42 yr Mixed (1-36 mo)	Serious: Complications due to surgical procedure in 6 pts (20%), and 9 pts (32%) experienced morbidity following procedure; wound infection, perineovaginal fistula, chest infection, hernia, stitch sinus, impaction, and prolapse of stoma most common. Other: Minor adverse effects not reported.
Nikiteas, 1996[99]	Efficacy of anal sphincter repair over a 5 yr period	N: 42 76% NR overall Mixed 38 mo (median) (12-66 mo)	Serious: Surgical complications in 2 pts (5%); breakdown of sphincter repair due to sepsis most common. Both pts required reoperation. Other: Minor adverse effects not reported.
Gibbs, 1993[100]	Efficacy of overlapping sphincter repair over a 9 yr period	N: 36 94% 47 yr Mixed 43 mo (4-114 mo)	Serious: Surgical complications in 2 pts (6%); both pts experienced wound sepsis requiring colostomy. Postoperative complications in 11 pts (31%); voiding difficulties, urinary tract infection, perianal sinus tract, and anal stenosis most common. Other: Fever and diarrhea reported in 1 pt (3%).
Keighley, 1984[101]	Efficacy of postanal repair	N: 105 92% 61 yr* Mixed 6 mo	Serious: One pt (1%) died following surgery. Wound sepsis reported in 8 pts (8%). Wound infection reported in 9 pts (11%). Skin necrosis reported in 22 pts (25%).Other: Bruising reported in 19 pts (21%).

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
SNS			
Moya, 2014[102]	Long-term efficacy of sacral nerve stimulation (SNS) for FI	N: 50 81% 64 yr Mixed 55 mo (mean)	Surgical: Infection at implant site reported in 1 pt (2%). Explant of device required in 3 pts (6%) due to pain at implant site and extremity pain that did not resolve with medical management. Other: Minor adverse effects not reported.
McNevin, 2014[103]	Efficacy of SNS (Interstim) for FI over a 2 yr period	N: 33 91% 63 yr Mixed NR	Surgical: Explant of device in 1 pt (3%) due to chronic pain.
Maeda, 2014[104]	Long-term efficacy of SNS for FI	N: 101 91% 57 yr NR 5 yr	Surgical: By the end of followup, device switched off or explanted in 24 pts (24%); loss of efficacy, lack of efficacy, pain, discomfort, and infection most common. Authors report 521 reportable events in 94 pts (93%); loss of efficacy, lack of efficacy, and pain/discomfort most common. Other: Minor adverse effects not reported.
Feretis, 2013[105]	Mid-term efficacy and safety of SNS for FI	N: 38 95% 62 yr* Mixed 16 mo (median) (3-42 mo)	Serious: Authors reported no infections, no major complications during implantation. Reoperation required in 3 pts (8%); need for battery replacement, fractured leads due to falls most common. Short-term complication (<30 d.) in 1 pt (3%); wound-site hematoma. Long-term complications in 24 pts (75%); loss of efficacy, need for re-programming.
Damon, 2013[106]	Long-term efficacy of SNS for FI	N: 119 95% 61 yr Mixed 48 mo (12-84 mo)	Surgical: During followup, explant in 10 pts (8%); lack of efficacy and pain most common reasons. Change in simulator and/or electrode required in 29 pts (24%). Pain reported in 29 pts (24%). Other: Minor adverse effects not reported.
Hull, 2013[107]	Long-term durability of SNS for chronic FI	N: 76 92% 61 yrs. Mixed 74.4 mo (60-96 mo)	Serious: Eight events in pts with 5-yr followup (11%). Implant site pain, site infection, and battery depletion most common. Reoperation in 36% overall for device revision (8%), replacement (32%), or explant (4%). Other: 218 events reported overall at 5-yrs. Paresthesia, change in sensation of stimulation, and urinary incontinence most common minor adverse effects
Faucheron, 2012[108]	Efficacy of SNS for patients with both FI & UI	N: 57 95% 58 yr Mixed 63 mo (mean)	Serious: Reoperation required in 16 pts (28%); infection, electrode displacement, pain, battery depletion, and loss of efficacy most common. Explant in 1 patient (2%). Complications in 7 pts (12%); details reported elsewhere. Other: Minor adverse effects not reported.

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
Pascual, 2011[109]	Short-term efficacy and safety of SNS for FI	N: 50 90% 60 yr Mixed 17 mo (mean)	Serious: Complications reported in 6 pts (12%); wound infection requiring explant, pain, externalization in gluteal stimulator, and broken electrode most common.
Mellgren, 2011[110]	Short- and long-term efficacy and safety of SNS for FI	N: 120 92% 62 yr Mixed 3.1 yr (mean)	Serious: Infection reported in 12 pts (10%). Other: Minor adverse effects reported in 65 pts (54%); implant site pain, paresthesia, and change in sensation of stimulation most common.
Maeda, 2011[111]	Incidence of suboptimal therapeutic response and adverse effects of SNS used in treatment of FI	N: 176 90% 61 yr* NR 11 mo (median) (4-26 mo IQR)	A total of 592 events reported in 150 pts (85%). Explant of device in 31 pts (19%); loss of efficacy, lack of efficacy, pain/discomfort, and infection most common. Most common reportable events were loss of efficacy (212 events in 87 pts [49%]), lack of efficacy (186 events in 68 pts [39%]), and pain or discomfort (126 events in 67 pts [38%]). Other: Constipation in 1 pt (1%), dizziness in 1 pt (1%) were the most common minor adverse effects.
Wexner, 2010[112]	Efficacy and safety of SNS for FI	N: 120 92% 62 yr Mixed 28 mo (2-70 mo)	307 AE occurred in 96 pts related to the device or therapy; 26 were serious. 13 (11%) implant site infections of which 7 needed surgery and 5 of the 7 were device explants; 2 replacements. After implantation, AE in at least 5% of pts: pain, paresthesias and infection most common; urinary incontinence, diarrhea and related sensory changes less common.
Michelsen, 2010[113]	Long-term efficacy and safety of SNS for FI at a single institution	N: 177 90% 60 yr Mixed 24 mo (3-72 mo)	Serious: Infection reported in 2 pts (2%). Failure of device requiring revision in 16 pts (13%). Explant in 15 pts (12%); decreased function, pain, technical failure, and infection most common. Other: Minor adverse effects not reported.
Faucheron, 2010[114]	Determine causes of surgical revision for patients receiving SNS for FI	N: 87 85% 56 yr Mixed 49 mo (2-96 mo)	Serious: Surgical revision required in 36 of 87 pts (41%) receiving permanent implant; infection, electrode displacement or breakage, pain, battery depletion, and loss of clinical efficacy most common reasons. Reoperation due to device malfunction required in 20 pts (23%). Successful revision in 12 pts (14%), explant in 12 pts (14%), details unclear in remaining 12 pts (14%) with surgical revision.
El-Gazzaz, 2009[115]	Efficacy and safety of sacral neuro-modulation on FI symptoms among pts with both UI & FI	N: 24 100% 57 yr NR 28 mo (3-49 mo)	Serious: Complications in 8 pts (33%); infection and lack of clinical response most common reasons; explant in 2 pts (8%). Other: Minor adverse effects not reported.

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
Hetzer, 2007[116]	Long-term efficacy and safety of SNS for FI	N: 44 68% 65 yr Mixed 13 mo (1-42 mo)	Serious: Complications requiring reoperation reported in 8 pts (22%); seroma, infection, pain, and loss of efficacy most common. Successful re-implant in 5 pts (14%). Other: Sleep disturbances reported in 2 pts (5%).
Rasmussen, 2004[117]	Efficacy and safety of SNS for FI	N: 45 75% 59 yr Mixed 6 mo (median) (0-36 mo)	Serious: Complications reported in 5 pts (14%); infection and lack of clinical response most common reason. Explant required in all 5 pts, and 2 pts with infection awaiting reimplantation at time of manuscript submission. Other: Minor adverse effects not reported.
Jarrett, 2004[118]	Efficacy of SNS for FI across 3 centers	N: 46 87% 56 yr* Mixed 12 mo (median) (1-72 mo)	Serious: Authors report that no major complications were observed. Complications in 8 pts (17%); skin infection, lead displacement, and pain most common. Other: Minor adverse effects not reported.
Kenefick, 2002[119]	Efficacy and safety of SNS for FI over a 5 yr period	N: 15 93% 60 yr Mixed 24 mo (median) (3-60 mo)	Serious: Although authors report no major complications or infections, permanent lead dislodgement requiring reoperation reported in 2 pts (13%). Other: Minor adverse events reported in (27%); pain, superficial skin infection most common.
Mixed/Other			
Boenicke, 2012[120]	Efficacy and safety of SNS for FI pts undergoing stapled transanal rectal resection (STARR)	N: 31 received STARR, 12 SNS 100% 70 yr Mixed 12 mo	Serious: Failure of SNS reported in 6 of 12 pts (50%) who received adjuvant SNS; reasons for failure not reported. Other: Minor adverse effects not reported.
Hultman, 2006[121]	Long-term efficacy of functional gluteoplasty	N: 25 88% 42 yr Mixed 21 mo (3-68 mo)	Serious: Complications reported in 16 pts (64%); dysthesias, cellulitis, irregular contour, abscess, seroma, and fistula most common. Failure of procedure in 2 pts (8%), both of who required permanent ostomy. Other: Minor adverse effects not reported.
Sphincter replacement			
Darnis, 2013[122]	Short- and long-term efficacy and safety of the Acticon® Neosphincter	N: 21 71% 51 yr	Serious: All patients experienced at least 1 surgical complication; infection or cutaneous ulceration, perianal pain, and rectal evacuation most common. Explant occurred in 17 pts (81%).

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
	artificial bowel sphincter (ABS)	Mixed 38 mo (12-98 mo)	Other: Minor adverse effects not reported.
Wong, 2011[123]	Long-term efficacy and safety of the Acticon® Neosphincter ABS	N: 52 (85 devices) 88% 52 yr Mixed 64 mo (2-169 mo)	Serious: 26 pts (50%) required revision of original surgery, leak due to perforation was most common reason. Explant occurred in 14 pts (27%), infection most common reason. Other: Minor adverse effects not reported.
Michot, 2010[124]	Efficacy of Acticon® Neosphincter ABS with a transvaginal (rather than perineal) approach	N: 32 100% 63 yr Structural 41 mo (18-75 mo)	Serious: Serious complications within 6 mo. of operation in 9 pts (28%) requiring explant of ABS; septic adverse event, poor function, and psychological problems cited as reasons Other: Minor adverse effects not reported.
Ruiz Carmona, 2009[125]	Long-term efficacy and safety of the Acticon® Neosphincter ABS	N: 17 82% 46 yr Mixed 68 mo (3-133 mo)	Serious: All patients experienced at least 1 surgical complication, and at least 1 reoperation required in 65% of pts; erosion and infection most common. Explant occurred in 11 pts (65%), after which 7 had a new implant. Other: Minor difficulties in rectal emptying in 3 patients (18%).
Melenhorst, 2008[126]	Efficacy of the Acticon® Neosphincter ABS	N: 33 76% NR NR 17 mo (1-106 mo)	Serious: Infection requiring removal of ABS in 7 pts (21%). Perianal pain without infection requiring colostomy in 1 pt (3%). Other: Minor adverse effects in 12 pts (36%); rectal evacuation problems needing conservative management most common.
Casal, 2004[127]	Efficacy of the Acticon® Neosphincter ABS	N: 10 (12 procedures) 80% 56 yr Mixed 29 mo (mean)	Serious: Postoperative complications in 6 pts (60%); abdominal wound, superficial dehiscence of the perianal wound, infection of the perianal wound, perianal hematoma most common. Explant occurred in 3 pts (30%), after which 2 had a new implant. Other: Minor adverse effects not reported.
Parker, 2003[128]	Efficacy of the Acticon® Neosphincter ABS at a single institution Group I: retrospective Group II: prospective	N: 45 60% 44 yr Mixed I: 91mo(29-143 mo) II: 39 (12-60 mo)	Serious: Procedure was unsuccessful in 2 pts (4%). Complications occurred in 16 pts (36%); infection, fluid leak, pain most common. Revision required in 13 pts (29%) and complete device replacement in 7 (16%), for a total of 21 revision procedures. Infections occurred in 19% of revisions. Explant of the ABS occurred in 18 pts (40%). Of these, 9 pts (20%) received stoma. Other: Constipation in 4 pts (9%).
Wong, 2002[12]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 112 (185 procedures) 77% 49 yr Mixed 1 yr	Serious: Total of 384 surgical complications occurred in 99 pts (88%). Of these, 246 required minimal to no intervention. Complications were infections. A total of 73 surgical revisions required in 51 pts (46%). Explant of the ABS in 41 pts (37%), after which 7 had a new ABS implanted. Other: 30 pts (27%) reported constipation; 21 pts (19%) reported impaction.

Author, Year	Study Aim	Number of Patients % Female Mean Age/Median* FI Etiology Followup (Range)	Adverse Effects of Surgical Treatment: Serious, Other
Ortiz, 2002[129]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 22 (24 procedures) 77% 47 yr Mixed 28 mo (6-48 mo)	Serious: Complications occurred in 17 pts (77%). Postoperative complications in 9 pts (41%); of these, 2 required reoperation due to perineal infection. Long-term complications in 10 pts (45%); of these, 9 required reoperation. Explant of the ABS in 7 pts (32%).
Davesa, 2002[130]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 53 66% 46 yr Mixed 26.5 mo (7-55 mo)	Serious: Perioperative complications in 14 pts (26%); abnormal bleeding, vaginal perforation, rectal perforation most common. Early complications in 16 pts (30%); sepsis, wound complication most common. Late complications in 29 pts (55%); impaction, cuff and/or pump erosion, pain, infection, mechanical failure most common. Explant occurred in 10 pts (19%). Other: Diarrhea in 4 pts (8%).
Altomare, 2001[131]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 28 100% 58 yr Mixed 19 mo (7-41 mo)	Serious: Complications in 18 pts (64%). Early infection in 4 pts, removal required in 3 of these pts. Dihiscence of perineal wound in 9 pts. Problems with cuff in 5 pts (rectal erosion, anal pain, late infection, malfunction). Explant occurred in 5 pts (18%). Other: Minor AE in 14 pts (50%); obstructed defecation, anal pain most common.
O'Brien, 2000[132]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 13 77% 44 yr* Mixed NR	Serious: Explant required in 3 pts (23%): 1 pt (7%) with early wound infection and 2 pts (15%) due to late complications (infection and skin erosion). Other: Minor adverse effects not reported.
Lehur, 2000[133]	Efficacy and safety of the Acticon® Neosphincter ABS	N: 24 71% 44 yr* Mixed 20 mo (10-35 mo)	Serious: Perineal wound dehiscence in 2 pts (8%). Explant occurred in 7 pts (29%), after which 3 had a new implant. Other: Minor adverse effects in 9 pts (38%); minor and major rectal emptying difficulties most common.
Christiansen, 1999[134]	Long-term efficacy and safety of artificial anal sphincter (AAS) [using a urinary sphincter and a modified urinary sphincter]	N: 17 65% 46 yr * Mixed 7 yrs (5-10 yrs)	Serious: Complications occurred in 7 pts (41%); infection and malfunction most common and explant was required in these 7 pts. 2 pts (12%) died in the first 3 yrs of followup of unrelated causes. Five of 8 pts with functioning AAS after 5 yrs required surgical revision procedures early on. Other: Minor adverse effects in 1 pt (6%); rectal emptying difficulties.

* Age reflects median age AAS=artificial anal sphincter (American Medical Systems AMS 800 urinary sphincter); ABS=artificial bowel sphincter; ACE=antegrade continence enema; AE=adverse event; d=day; FI=fecal incontinence; MACE=Malone antegrade continence enema; mo=months; NR=not reported; pt=patient; pts=patients; SNM=sacral neuromodulation; SNS=sacral nerve stimulation; UI=urinary incontinence; yr=years

Table F10. KQ 1: Benefits of treatment: Summary and strength of evidence of effectiveness and comparative effectiveness of treatments for fecal incontinence in adults by strength of evidence domains*

Intervention	Outcome: Change From Baseline	Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence	Findings
Dietary fiber supplementation with psyllium vs. placebo	FI episodes per week	1 RCT[54] N=206	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	Psyllium significantly decreased FI by 2.5 episodes per week vs. placebo (0.7 fewer episodes/week) at 1 month
Clonidine (oral) 0.2mg/day vs. placebo	Mean weekly FICA	1 RCT[53] N=44	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	No significant difference between groups in FICA improvement at 1 month (1.6 points clonidine vs 1.5 placebo)
PFMT-BF plus estim vs. PFMT-BF	CCFIS	2 RCTs[45, 48] N=109	Medium	Consistent	Direct	Imprecise	Undetected	Low	No significant difference between groups in mean CCFIS improvement at 3 months: -1 point in both groups;[45] -2 points treated, -2.5 points control[48]
	FIQL	2 RCTs[45, 48] N=109	Medium	Consistent	Direct	Precise	Undetected	Low	No significant difference in FIQL between groups at 2 to 3 months; neither group improved (0 to 0.3 point change from baseline per subscale)
Dextranomer tissue bulking injections vs. PFMT-BF +/- estim	Vaizey score	1 RCT[65] N=126	Low	Consistency unknown (single study)	Direct	Imprecise	Detected (EQ-5D at 6 mo. NR)	Low	No significant difference between groups in Vaizey improvement at 6 months (-4.6 points dextranomer vs. -5.4 points PFMT-BF)
	FIQL	1 RCT[65] N=126	Low	Consistency unknown (single study)	Direct	Imprecise	Detected (EQ-5D at 6 mo. NR)	Low	No significant difference between groups in FIQL at 6 months (per text and figures; values NR)

Intervention	Outcome: Change From Baseline	Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence	Findings
Dextranomer tissue bulking injections vs. sham injections	CCFIS	1 RCT[40] N=206	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	No significant difference between treated vs. sham in CCFIS improvement at 3 months (-2.6 points dextranomer vs. -2 sham) and 6 months (-2.5 points dextranomer vs. -1.7 sham)
	FI severity: Percent of patients with ≥50% reduction in FI episodes Median decrease in number of FI episodes/ 2 weeks Mean increase in number of FI-free days	1 RCT[40] N=206	Low	Inconsistent (3 measures gave inconsistent results: 2 better, 1 no different)	Direct	Imprecise	Undetected	Low	Significant difference in percent of patients with ≥50% reduction in FI episodes at 6 months: 52% of dextranomer group vs. 31% sham. Median decrease in number of FI episodes over 2 weeks was not significantly different between groups at 3 months or 6 months (6.0, IQR 0-12.5) vs. 3.0 sham, IQR 0-8.9: p=0.09). Mean increase in number of FI-free days was greater in treated (3.1 days, SD 4.1) vs. sham (1.7 days, SD 3.5) group
	FIQL	1 RCT[40] N=206	Low	Consistency unknown (single study)	Direct	Imprecise	Undetected	Low	Percent improvement from baseline in FIQL coping-behavior subscale favored dextranomer at 6 months: 27% (CI 21%, 34%) vs. sham 11% (CI 3%, 18%). Change scores in 3 other FIQL subscales did not differ (per text and figures, values NR)

Intervention	Outcome: Change From Baseline	Number of Studies	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Strength of Evidence	Findings
Durasphere® (off-label) tissue bulking injections vs. non-FDA approved PTQ™ injections	CCFIS	2 RCTs[38, 43] N=75	Low (2)	Consistent	Direct	Imprecise	Undetected	Moderate	Moderate evidence that Durasphere® (off-label) injections reduce FI severity at 6 months, and that benefit diminishes between 6 months and 1 year**: 5.3 points at 6 weeks, 4.1 at 6 months,1.8 at 1 year, [38] 3.8 points at 6 weeks, 5.3 at 6 months, 4.5 at 1 year[43]

*Table shows strength of evidence for treatment-outcomes combinations with at least 2 moderate risk of bias RCTs or 1 RCT with low risk of bias and sufficient power to assign low strength of evidence. Other comparisons that had insufficient evidence are not shown in the table.

**Non-FDA approved comparator PTQ™ results are not discussed.

+/- = with or without; BF=Biofeedback; CCFIS=Cleveland Clinic Fecal Incontinence Score; C=Comparator/control; EQ-5D=EuroQoL Questionnaire-5 Dimensions; Estim=Electrostimulation; FI=Fecal incontinence; FIQL=Fecal Incontinence Quality of Life scale; FDA=Food and Drug Administration; M=Mahoney 2004; N=Naimy 2007; NR=not reported; PFMT=Pelvic floor muscle training; PTQ™=injectable bulking agent not FDA approved for use in the US; RCT=randomized controlled trial; T=Treatment group Vaizey=Vaizey Fecal Incontinence Score

Table F11. Risk of bias ratings for randomized clinical trials of fecal incontinence treatments

Author, Year	Intervention	Risk of Bias	Rationale
Bliss 2014[54]	Dietary fiber	Low	Randomized study with allocation concealment; patients and outcome assessors blinded, likely providers too. Adjusted for multiple comparisons; ITT; all relevant outcomes reported; good description of treatments; diagram shows LTF information
Bliss 2001[20]	Dietary fiber	Moderate	Randomization described, single blind study, unclear reporting (whether 42 or 39 patients were randomized, or if the 3 patients who discontinued did so before randomization); primary outcome not specified; ITT. Very limited baseline information on sample (in text).
Lauti, 2008[57]	Dietary fiber and loperamide	Moderate	Low risk of selection bias. Patients and clinicians reportedly blinded but diet advice sheets regarding fiber were common public knowledge at that time (hence, diet unblinded but fiber supplement was deidentified). Non-standardized dietary intervention. Reported ITT but unclear how missing data from 16 was handled in analysis.
Park 2007[58]	Topical phenylephrine	High	Excluded post-randomization data from 6 of 35 with poor compliance. Primary outcome NR. Randomization and allocation low risk. Blinding of pts not possible. Unclear if outcomes assessors were blinded (NR)
Carapeti 2000[64]	Topical phenylephrine	Moderate	Low risk of selection bias. Patients and providers blinded; unclear if outcome assessors blinded. Co-intervention (loperamide) allowed in 42% of patients throughout study; attrition unclear (tables do not show number assessed and LTF NR)
Carapeti 2000[62]	Topical phenylephrine-ileoanal pouch	High	Limited baseline data (in text); patients and providers blinded; blinding of outcome assessors NR; primary outcome NR. Low risk of selection bias. Only period 1 data of crossover were analyzed (washout period may have been insufficient). Cointervention (loperamide) used by 2/3 of sample throughout study.
Sun 1997[27]	Loperamide	High	No baseline data, not all outcomes reported and no justification for why FI counts NR; no details on blinding, allocation concealment, or blinding of outcome assessors
Hallgren 1994[14]	Loperamide	Moderate	Limited baseline information (age, sex in text); no baseline values of outcomes, no details on allocation concealment, or blinding of outcome assessors
Read 1982[30]	Loperamide	Moderate	Reported as double blind but no information on randomization mechanism; allocation concealment unclear. No baseline data on outcomes; primary outcome NR.
Palmer 1980[22]	Mixed antidiarrheals	High	No baseline data except etiology; noncompleters excluded from analysis (17%); No information on randomization mechanism; blinding and allocation concealment NR; Primary outcome not specified.
Bharucha 2014[53]	Clonidine	Low	Blinded study, random allocation, low attrition, ITT analysis with methods for missing data, validated outcome measures, all outcomes are reported at 4 weeks.
Pinedo 2012[39]	Zinc-aluminum ointment	Moderate	Unclear risk of bias in several domains due to unclear reporting. Between and within group completer analysis. Needed 48, analyzed 44.
Pinedo 2009[42]	Topical estrogen	Moderate	Double blind stated; NR if outcome assessors were blinded. Randomization method NR. Low attrition; excluded data from 1 placebo pt. who did not complete therapy. All outcomes reported
Kusunoki 1990[25]	Sodium valproate	Moderate	Random order assignment but method not specified. No information on allocation concealment, or whether anyone was blinded. Limited sample, baseline information reported. Primary outcome not specified.

Author, Year	Intervention	Risk of Bias	Rationale
Damon 2014[37]	PFMT-BF	High	Patients lost to followup were excluded from the analysis. Groups unbalanced at baseline for important prognostic factor (history of anorectal surgery). Inadequate randomization detail, allocation NR. Patient and provider blinding not possible.
Norton 2003[33]	PFMT-BF	Moderate	Low risk of selection bias: randomization and allocation concealment acceptable. Blinding of patients and providers not possible. Attrition 18% overall and differed by group (some over 20%); reasons for withdrawal vague. Implications of LTF not discussed. ITT.
Heymen 2009[15]	PFMT-BF	Moderate	No allocation concealment, providers not blinded. Run-in period followed randomization, then treatment failures at run-in commenced interventions with imbalance in group size; baseline considered end of run in and comparability at that point was NR. Attrition 23%.
Whitehead 1985[56]	PFMT-BF	High	Unclear risk of selection bias (randomization and allocation not reported, group comparisons at baseline not reported); no blinding of patients, providers or outcomes assessors, intervention details not described; cointerventions NR, attrition NR.
Ilnyckyj 2005[55]	PFMT-BF	High	Selection bias: unclear risk (randomization and allocation not reported, group comparisons at baseline NR). LTF 22% and no mention of implication of LTF or how missing data handled. No blinding of patients, providers or outcomes assessors.
Bols 2012[66]	PFMT-BF	Moderate	Low risk of selection bias. Patients and providers not blinded; outcome assessors blinded. Multiple providers. High risk of detection bias (followup varied, very underpowered before attrition). ITT.
Solomon 2003[59]	PFMT-BF	High	Provider and patients not blinded to treatment, cointerventions (patients on BF continued previous treatments); handling of missing data NR, analysis of completers likely.
Bartlett 2011[26]	PFMT-BF exercise	High	Groups unbalanced at baseline for important prognostic factor (history of bowel surgery for cancer). Patients blinded but providers and outcomes assessors not blinded. Only 73% of participants analyzed at 2 yr. Randomization and allocation concealment acceptable.
Schwandner 2011[19]	PFMT-BF electrostimulation	Moderate	Providers and patients not blinded; outcome assessors blinded. LTF 11% (reasons for withdrawal vague), select outcomes reported
Schwandner 2010[41]	PFMT-BF electrostimulation	High	Patients who deteriorated were combined with drop outs and no change pts. in analysis; percent who deteriorated were not separately identified. Patients and providers not blinded; outcome assessors blinded. Attrition 61%.
Naimey 2007[45]	PFMT-BF with electrostimulation	Moderate	No baseline characteristics table; no blinding of providers, patients or outcomes assessors. LTF 18%, no mention of how LTF or missing handled. Analysis not ITT.
Mahoney 2004[48]	PFMT-BF with electrostimulation	Moderate	Completer analysis. Pts not blinded, providers blinded, outcomes assessors not blinded; adequate randomization and allocation concealment
Fynes 1999[61]	PFMT-BF with electrostimulation	High	No baseline data, group comparisons at baseline NR, blinding not possible, multiple providers.
Norton 2006[63]	Electrostimulation	Moderate	Poor treatment fidelity; patients, providers and outcomes assessors were unblinded; lacks baseline characteristics by group; attrition 23%
Healy 2006[46]	Electrostimulation	High	Analyzed completers only. Aim was a care site comparison but treatments also differed by group (duration & protocol). Limited baseline characteristics reported. Attrition 17%

Author, Year	Intervention	Risk of Bias	Rationale
Christensen 2006[18]	Transanal irrigation	Moderate	Randomization & allocation low risk; blinding of patients not possible. Weekly interviewer blinded. Cointerventions allowed as needed. ITT. LTF reported overall and by group. Handling of missing data acceptable. No correction for multiple testing. More pts in wheelchairs in control group.
Coggrave 2010[52]	Stepwise bowel management intervention	High	Low risk of selection bias. Blinding not possible. High (35%) overall attrition and unequal by group (attrition higher in treatment group), poor treatment fidelity
Schnelle 2010[17]	Exercise plus diet	High	FI outcome difficult to analyze: 45% of residents did not have a bowel movement during baseline or 10 days post-intervention. Difference between groups at baseline on some important factors. No blinding of patients or providers but validity checks done. Multi-component intervention and multi-center.
Schnelle 2002[16]	Exercise plus incontinence care	High	Low risk of selection bias. Noncompleters dropped from analysis; impact of LTF discussed. High attrition, blinding of patients not possible. FI outcomes not presented for 2 months, only 8 months. Primary outcome not specified
Thin 2015[36]	PTNS	Moderate	Low risk of selection bias. Adequate randomization, blinded (providers and assessors). Patient blinding not possible. Groups differed at baseline on important variables (prior/ongoing treatments including pad use, antidiarrheal drugs and biofeedback; evacuatory difficulties; FI etiology). No significance testing conducted; no between-group analyses. Small sample size; excluded post-randomization data on 23% of sample.
Dehli 2013[65]	Dextranomer injections	Low (to 6 mo)	Low attrition for 6 month analysis. Random allocation and blinded to the extent they were able. PFMT/BF intervention poorly described. ITT analysis with methods for missing data provided. Dismissed 44% of sample at 6 mo. for observational study.
Graf 2011[40]	Dextranomer injections	Low (to 6 mo)	Adequate randomization, blinded (patients and assessors) up to 6 mo, low attrition to 6 mo, sham group had nothing injected (unclear if pts could tell that nothing was injected); Multicenter and multiple providers
Morris 2013[38]	Durasphere injections	Low	Adequate randomization, blinding, allocation concealment; low attrition, sufficient description of treatments, underpowered study (because trial stopped early), lacks demographic information
Tjandra 2009[43]	Durasphere injections	Low	Adequate randomization, allocation concealment; no details on blinding of outcome assessors and not possible to blind surgeons; sufficient description of treatments. No attrition.
Davis 2004[47]	Surgery	High	Blinding of patients not possible, limited sample information, unclear reporting (Fig. 1 participant flow does not account for all lost-to-follow-up; unclear if excluded adults differed on FI severity, etc.). Excluded post-randomization data on 18% of sample.
Hasegewa 2000[50]	Surgery	High	Randomized but no details on method of randomization or allocation concealment. Unclear whether patients and outcome assessors were blinded; blinding not possible for surgeons. Followup varied (no defined assessment point). No baseline table, limited demographic information in text only; no information on co-interventions.
O'Brien 2004[49]	Surgery	High	Blinding not possible; no information on outcome assessor blinding; sparse detail on comparator, no information on co-interventions. Excluded patient failed treatment and required colostomy from analysis. Limited demographic information.
Yoshioka 1999[21]	Surgery	Moderate	No information on blinding of patients or outcomes

Author, Year	Intervention	Risk of Bias	Rationale
			assessors. Multiple descriptions of followup duration. Primary outcome not specified. Surgeons had limited experience with control surgery. No statistical comparison of between group differences at any time point for any outcome.
Osterberg 2004[29]	Surgery	High	Non-completers excluded from analysis (16%). LTF differed by group (13% vs. 25% anal plug). Blinding of patients and providers not possible; blinding of outcomes assessors NR. No information on co-interventions, primary outcome not specified
van Tets 1998[34]	Surgery	Moderate	Unclear if patients or outcome assessors were blinded. Primary outcome not specified. Multiple descriptions of followup duration (1.5-5 years) but outcomes reportedly assessed at 3 months. No statistical comparison of patient reported outcome measure, no information on allocation concealment, no information on co-interventions
Deen 1993[51]	Surgery	High	No information on allocation concealment, no information on co-interventions, primary outcome not specified, FI frequency not reported at 6mo. and other data (FI severity) not usable.
Duelund-Jakobsen 2013[31]	SNS	Moderate	Patients blinded; NR if outcomes assessors were blinded. Limited baseline sample information. No adjustment for multiple comparisons. LTF not clearly stated and sample size (denominators) not reported in results tables. Primary outcome NR.
Duelund-Jakobsen 2012[23]	SNS	High	Randomization NR only allocation concealment; sparse demographic/sample baseline data (in text). Unclear if outcome assessors blinded. Cointerventions NR. Unblinded after 12 wks and followed only part of the sample.
Tjandra 2008[44]	SNS	Moderate	Patient and provider blinding not possible, primary provider assessed outcomes. Outcomes only partially reported. Randomization and allocation concealment adequate.
Michelsen 2008[24]	SNS	High	No baseline values reported for any measure; crossover RCT but no washout period; excluded data from drop-out. Blinding of outcome assessors NR; not possible to blind patients or providers.
Leroi 2005[28]	SNS	High	Few details on randomization, primary outcome unclear. Patients blinded. Selective reporting: not all outcomes collected were reported; unclear what statistical comparisons being made, no adjustment for multiple comparisons. LTF dropped from analysis (13%)

+/-=with or without; BF=biofeedback; FI=fecal incontinence; ITT=intention to treat analysis; LTF=lost to followup; mo=months; NR=not reported; PFMT=Pelvic floor muscle training; PTNS=percutaneous tibial nerve stimulation; Pts=patients; SNS=sacral neurostimulation

Table F12. Risk of bias in fecal incontinence observational studies with comparison group

Author, Year	Treatment	Risk of Bias*	Rationale
Sze, 2009[68]	Fiber & loperamide	High	Comparison group was patients who declined treatment; range and median followup NR; groups differed by unrelated medical history at baseline; prospective study
Remes-Troche, 2008[69]	PFMT-BF + drug	Moderate	Prospective design. Followup duration similar between groups. Comparator group randomly selected from database and matched for gender, age, and FI severity.
Byrne, 2005[70]	PFMT-BF	Moderate	Prospective design. Range of followup NR (median=42 mo). Groups similar at baseline for several characteristics. Lacks some FI severity information at baseline.
Loening-Baucke, 1990[71]	PFMT-BF +/- medical	High	No statistical comparison between group characteristics at baseline; analyses did not control for baseline differences between groups. Prospective design; groups treated at different times (BF: 1983-1985; medical: 1985-1987).
van der Hagen, 2012[72]	Irrigation*	High	Prospective design. Range and median followup NR. Groups differed at baseline on etiology and prior treatments. Analyses conducted and results reported separately by FI type (passive vs soiling). Analyses did not control for baseline differences between groups.
Wong, 2011[75]	Surgery*	High	Wide range of followup (6-72 mo). Median followup differed by group (8 mo vs 22.5 mo). Prospective design, small sample.
Dudding, 2009[77]	Surgery	High	Retrospective design. Wide range of followup (1-106 mo). Median followup differed by group (8 mo vs 51 mo).
Steele, 2006[78]	Surgery	High	Retrospective design. Mean followup differed by group (27 mo vs 44 mo); range of follow-up NR. Groups differed at baseline on important variables (rectocele, manometry). Wide range of etiologies.
Briel, 1998[81]	Surgery	High	Retrospective design. Range and median followup NR (range at least 10-24 mo). Historical controls used as comparator group (evaluated during 1973-1988 vs 1989-1994). Baseline characteristics not compared between groups. Etiologies NR.
Osterberg, 2000[80]	Surgery	High	Prospective design. Etiology determined treatment allocation. Followup similar between groups. Groups differed by age at baseline.; analysis did not control for baseline differences between groups.
Tan, 2001[79]	Surgery	Moderate	Retrospective design. Groups were sequential over5-year recruitment (first 64% of sample received 1 type of incision; more recent sample another) therefore wide range of followup. Groups similar on key characteristics at study initiation.
Hong, 2014[73]	Surgery vs. SNS	High	Retrospective design. Wide range of followup (3-138 mo). Mean followup differed by group (50 mo vs 36 mo vs 38 mo). At baseline groups differed by etiology, 2+ failed previous sphincteroplastics, and endoanal ultrasound.
Wong, 2012[74]	Surgery* vs. SNS	High	Comparator group (MAS) had previously failed treatment group procedure (SNS). Retrospective design. Wide range of followup (8-30 mo) and followup differed by group (18 mo vs 2 mo). Groups similar at baseline for other key characteristics.
Ratto, 2010[76]	Surgery vs. SNS	High	Retrospective design. Wide range of followup (6-96 mo). Followup differed by group (60 mo vs 33 mo). Age NR at time of procedure.

*Comparator arm non-FDA approved - treatment arm reported only.
FDA=Food and Drug Administration; FI=fecal incontinence; mo=month; NR=Not Reported; SD=standard deviation; SNS=sacral nerve stimulation; yr=year

Table F13. Recommendations for treatments for fecal incontinence from professional society guidelines compared with MN EPC report findings

Treatment	American College of Gastroenterology (ACG)[135]	American Society of Colon and Rectal Surgeons (ASCRS)[136]	Minnesota EPC Report
Nonsurgical			
Dietary fiber	Not separately addressed	Not separately addressed	Low-strength evidence that dietary fiber supplementation with psyllium decreases FI frequency by 2.5 episodes per week after 1 month
Antidiarrheal drugs	Gastroenterologists and other providers should prescribe antidiarrheal agents for FI in patients with diarrhea (strong recommendation, low quality of evidence).	Not separately addressed	Low-strength evidence that clonidine has no effect; other drug evidence is insufficient
Combined: diet, medications, education, etc.)	Gastroenterologists and other providers should manage patients with FI using education, dietary modifications, skin care, and pharmacologic agents to modify stool delivery and liquidity before diagnostic testing, particularly when symptoms are mild and not bothersome (strong recommendation, moderate quality of evidence).	Dietary and medical management are recommended as first-line therapy for patients with FI. (Strong recommendation, low- or very low-quality evidence).	Not separately addressed; was a control group intervention only
PFMT-BF (any/all comparators)	Not addressed	Biofeedback should be considered as an initial treatment for patients with incontinence and some preserved voluntary sphincter contraction. (Strong recommendation, moderate-quality evidence.)	Low-strength evidence that PFMT-BF with estim is no more effective than PFMT-BF on FI severity and FI quality of life (FIQL) Insufficient evidence that PFMT-BF offers any advantage over standard care (such as dietary fiber, stool-modifying drugs.)
PFMT-BF vs. PFMT alone	Pelvic floor rehabilitative techniques are effective and superior to pelvic floor exercises alone in patients with FI who do not respond to conservative measures (strong recommendation, moderate quality of evidence).	Not separately addressed	Insufficient evidence
Bowel management program (enema, suppository)	Not addressed	Bowel management programs to aid in rectal evacuation are useful in select patients. (Weak recommendation, low- or very low-quality evidence.)	Insufficient evidence
Injectable anal sphincter tissue bulking agents	Minimally invasive procedures such as injectable anal bulking agents may have a role in patients with FI who do not respond to conservative therapy (weak recommendation, moderate-quality of	Injection of biocompatible bulking agents into the anal canal may help to decrease episodes of passive FI. (Weak recommendation, moderate-quality evidence.)	Low-strength evidence (6 months) that: *dextranomer injections are more effective than sham injections on FI quality of life, the number of FI-free days, and % with at least 50% reduction in FI episodes;

Treatment	American College of Gastroenterology (ACG)[135]	American Society of Colon and Rectal Surgeons (ASCRS)[136]	Minnesota EPC Report
	evidence).		* no more effective than PFMT-BF with or without estim on FI severity and FIQL; * no more effective than sham injection on FI severity (CCFIS) or FI frequency Moderate-strength evidence that Durasphere® (off-label) injections reduce FI severity (CCFIS) up to 6 months then gains diminish
Percutaneous tibial nerve stimulation (FDA approved for UI not FI)	Not addressed	Percutaneous tibial nerve stimulation may be considered because it provides short-term improvement in episodes of fecal incontinence. (Weak recommendation, low- or very low-quality evidence.)	Insufficient evidence
Surgical			
Sacral neurostimulation (SNS)	Sacral nerve stimulation should be considered in patients with FI who do not respond to conservative therapy (strong recommendation, moderate quality of evidence).	Sacral neuromodulation may be considered as a firstline surgical option for incontinent patients with and without sphincter defects. (Strong recommendation, moderate-quality evidence.)	Insufficient evidence
Anal sphincter repair (sphincteroplasty)	Anal sphincteroplasty should be considered in patients with FI who do not respond to conservative therapy and who have an anatomic sphincter defect (weak recommendation, low quality of evidence).	Sphincter repair (sphincteroplasty) may be offered to symptomatic patients with a defined defect of the external anal sphincter. (Strong recommendation, moderate-quality evidence.)	Insufficient evidence
Repeat anal sphincter repair	Not addressed	Repeat anal sphincter reconstruction after a failed overlapping sphincteroplasty should generally be avoided unless other treatment modalities are not possible or have failed. (Strong recommendation, low- or very low-quality evidence.)	Insufficient evidence
Artificial anal sphincter replacement	Artificial anal sphincter may possibly allow the occasional patient with FI to avoid colostomy (weak recommendation, insufficient evidence).	Implantation of an artificial bowel sphincter remains an effective tool for select patients with severe fecal incontinence. (Strong recommendation, low- or very low-quality evidence.)	Insufficient evidence

Treatment	American College of Gastroenterology (ACG)[135]	American Society of Colon and Rectal Surgeons (ASCRS)[136]	Minnesota EPC Report
Anatomic defect correction (prolapse, fistula, etc.)	Not addressed	Obvious anatomic defects such as rectovaginal fistula, rectal or hemorrhoidal prolapse, fistula in ano, or cloacalike deformity should be corrected as part of the treatment of fecal incontinence. (Strong recommendation, low- or very low quality evidence.)	Not addressed
Radiofrequency anal sphincter remodeling (SECCA)	There is insufficient evidence to recommend radiofrequency ablation treatment to the anal sphincter (SECCA) at this time (no recommendation, insufficient evidence).	Application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. (Weak recommendation, moderate-quality evidence.)	Insufficient evidence
Non-FDA approved surgeries	Dynamic graciloplasty may possibly allow the occasional patient with FI to avoid colostomy (weak recommendation, insufficient evidence).	Current data are insufficient to support the use of the magnetic sphincter for fecal incontinence. (Weak recommendation, low- or very low-quality evidence.)	Not addressed
Colostomy	Colostomy is a last resort procedure that can markedly improve the quality of life in a patient with severe or intractable FI (strong recommendation, low quality of evidence).	Creation of a colostomy is an excellent surgical option for patients who have failed or do not wish to pursue other therapies for fecal incontinence. (Low- or very low quality evidence.)	Not addressed

*In favor of unless otherwise noted

BF=Biofeedback; CCFIS = Cleveland Clinic Fecal Incontinence Score; estim= electrostimulation; FDA= Food and Drug Administration; FIQL=Fecal Incontinence Quality of Life measure; PFMT=Pelvic floor muscle training; UI = urinary incontinence

Appendix G. References

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